

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/21/98ISR Number: 3017741-3Report Type:Expedited (15-DaCompany Report #199712352HMRI Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Atrioventricular Block	Health	Diltiazem					
Hospitalization - Initial or Prolonged	Blood Gases Abnormal Hypotension	Professional	Hydrochloride	PS		ORAL	27000 MG ONCE	
	Intentional Overdose		Cannabis	SS		PO		
	Labile Blood Pressure		Cocaine	SS				
	Mydriasis		Hypnotic And					
	Pulmonary Oedema		Sedative Agents	SS				
	Pupil Fixed	..	C					
	Renal Failure							
	Respiratory Failure							
	Ventricular Extrasystoles							

Date:04/29/98ISR Number: 3072968-XReport Type:Expedited (15-DaCompany Report #8-98104-050N Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Cleft Palate	Literature	Antabuse	PS		ORAL	250 MG DAILY	
	Complications Of Maternal Exposure To Therapeutic Drugs		Crack Cocaine	SS		ORAL	CONCEPTION-2	
	Congenital Nail Disorder		Ethanol	SS		WEEKS	2 WK	
	Limb Malformation		Marijauna	SS		DDDDD	55 DAY	
	Small For Dates Baby					WEEKS	CONCEPTION-2	
		Antihistamine	C					
		Decongestants	C					

Date:05/14/98ISR Number: 3078858-0Report Type:Expedited (15-DaCompany Report #8-98125-056A Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Mydriasis Overdose	Foreign Health	Effexor	PS		ORAL	ORAL	
		Professional	Cannabis	SS		ORAL	ORAL	
			Ethanol	SS		ORAL		
			Thiamine	SS		ORAL		

Date:10/01/98ISR Number: 3260862-0Report Type:Periodic Company Report #001-0073-980069 Age:22 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Intentional Overdose	Health	Dilantin (Phenytoin					
		Professional	Sodium)	PS		ORAL	ORAL	
			Anti-Epileptic Medication					

(Unspecified) SS  
Marijuana (Cannabis) SS

INHALATION

21-Jul-2006 10:28 AM

Page: 1

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/02/98ISR Number: 3259845-6Report Type:Periodic Company Report #7396412 Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Consumer	Abbott - Depakote	PS	Abbott	ORAL	1.500 GM	PO
	Drug Level Below Therapeutic	Health Professional	Cannabis	SS		QD		
		Xanax	C					
		Wellbutrin	C					
		Trazodone	C					

Date:01/25/99ISR Number: 3185579-2Report Type:Expedited (15-DaCompany Report #JAUSA-35799 Age:1 DY Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Distension Akinesia	Health Professional	Risperdal Cocaine	PS SS	Janssen	ORAL ORAL	ORAL	ORAL
	Bowel Sounds Abnormal		Marijuana (Opiate Unspec.)	SS				
	Cardiac Murmur		Benzodiazepines	SS				
	Complications Of Maternal Exposure To Therapeutic Drugs	Zoloft	Depakote	C				
	Cyanosis	Ventolin	C					
	Grand Mal Convulsion							
	Hyperreflexia							
	Neonatal Complications Of Substance Abuse							
	Pallor							
	Petechiae							

Date:02/04/99ISR Number: 3405202-9Report Type:Periodic Company Report #98USA11257 Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Hallucination	Health Professional	Ritalin Tablet (Methylphenidate Hydrochloride)	PS		ORAL		DAILY, ORAL
	Insomnia		Marijuana (Cannabis)	SS		RESPIRATORY INHALATION		
	Overdose							
	Psychotic Disorder	Wellbutrin Tablet						

(Amfebutamone  
Hydrochloride) SS ORAL ORAL

Date:03/01/99ISR Number: 3427104-4Report Type:Periodic Company Report #A0075296 Age:28 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Aggression	Consumer	Zyban	PS	Glaxo Wellcome Inc	ORAL	150 MG	SINGLE
	Depression					DOSE ORAL		
	Drug Interaction		Cannabis	SS				
	Emotional Disorder							
	Mood Altered							
	Nightmare							

21-Jul-2006 10:28 AM

Page: 2

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/04/99ISR Number: 3212750-3Report Type:Expedited (15-DaCompany Report #1999-02-0367 Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Delirium	Health	Subutex					
	Mania	Professional	(Buprenorphine Hcl)					
	Mood Altered		Sublingual Tablets	PS		SUBLINGUAL	18 MG	QD
	Paranoia					SUBLINGUAL	3 YR	
		Cannabis	SS			OCCASIONALLY		
		Alepsal	C					

Date:06/24/99ISR Number: 3293262-8Report Type:Expedited (15-DaCompany Report #PRIUSA1999002552 Age:20 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Ultram (50 Mg					
	Drug Abuser	Health	Tablet) (Tramadol					
		Professional	Hydrochloride)	PS		ORAL		ORAL
			Marijuana (Cannabis)	SS				
			Benzodiazepine	SS		ORAL		ORAL

Date:07/30/99ISR Number: 3315458-9Report Type:Expedited (15-DaCompany Report #9932145 Age:28 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Brief Psychotic Disorder,	Consumer	Zoloft Tablets	PS		ORAL	100.00 MG	
Intervention to	With Postpartum Onset					TOTAL:DAILY:O		
Prevent Permanent	Depression					RAL		
Impairment/Damage	Dizziness		Alcohol	SS				

Drug Level Above Therapeutic  
 Feeling Abnormal  
 Ill-Defined Disorder  
 Mental Disorder  
 Road Traffic Accident

Marijuana  
 Ibuprofen

SS  
 C

Date:09/13/99ISR Number: 3346707-9Report Type:Expedited (15-DaCompany Report #JAUSA35799

Age:1 DY Gender:Male I/FU:F

Outcome PT  
 Hospitalization - Abdominal Distension  
 Initial or Prolonged Blood Ph Decreased  
 Bowel Sounds Abnormal  
 Caesarean Section  
 Cardiac Murmur  
 Complications Of Maternal  
 Exposure To Therapeutic  
 Drugs  
 Convulsion Neonatal  
 Cyanosis Neonatal  
 Drug Withdrawal Syndrome  
 Neonatal  
 Foetal Distress Syndrome  
 Haematocrit Decreased  
 Hyperreflexia  
 Intestinal Functional  
 Disorder  
 Maternal Use Of Illicit  
 Drugs

21-Jul-2006 10:28 AM

Page: 3

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Pallor  
 Pco2 Decreased  
 Petechiae  
 Ventricular Septal Defect

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Health Professional	Risperdal(Tablet) (Risperidone)	PS		ORAL		ORAL
	Cocaine(Cocaine)	SS		ORAL		ORAL
	Marijuana(Opiat)	SS		NASAL		INHALA
	Unspecified (Benzodiazepine Derivatives)	SS		ORAL		ORAL
	Depakote	C				
	Zoloft	C				
	Ventolin	C				

Date:09/27/99ISR Number: 3359040-6Report Type:Expedited (15-DaCompany Report #9461/18276

Age:35 YR Gender:Male I/FU:I

Outcome PT  
 Report Source  
 Product  
 Role Manufacturer  
 Route  
 Dose  
 Duration

Hospitalization - Overdose Health Od - Xanax Tablets PS ORAL OD-17-18 TAB  
 Initial or Prolonged Sedation Professional (S) / DAY  
 Other Suicide Attempt Other ORAL  
 Tachycardia Marijuana SS  
 Toxicologic Test Abnormal Amphetamine SS

Date:09/27/99ISR Number: 3359862-1Report Type:Expedited (15-DaCompany Report #USA/99/01758/LAS Age:32 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Health	Lamisil (Terbinafine	PS		ORAL	250 MG, ONCE	
	Drug Interaction	Professional	Hydrochloride)			A DAY, ORAL		
	Grand Mal Convulsion		Marijuana (Cannabis)	SS		1 CIGARETTE,		
			Dilantin	C		INHALATION 1 DAY		

Date:10/27/99ISR Number: 3383045-2Report Type:Expedited (15-DaCompany Report #9944977 Age:1 DY Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Complications Of Maternal	Foreign	Zithromax Capsules	PS		ORAL	ORAL	ORAL
	Exposure To Therapeutic	Health	Methylphenidate	SS		ORAL	ORAL	
	Drugs	Professional	Cannabis	SS				
	Polydactyly	Other						
	Pregnancy							
	Syndactyly							

Date:10/29/99ISR Number: 3386400-XReport Type:Expedited (15-DaCompany Report #HQ3490225OCT1999 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Alcohol Increased	Health	Effexor (Venlafaxine	PS		ORAL	1800 MG	
Initial or Prolonged	Dysarthria	Professional	Hydrochloride)			ORAL		
Other	Hypotension	Other				OVERDOSE		
	Overdose					AMOUNT		
	Respiratory Rate					ORAL	1 DAY	
	Increased		Cannabis (Cannabis)	SS		OVERDOSE		
	Sedation					AMOUNT		

21-Jul-2006 10:28 AM

Page: 4

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Diazepam (Diazepam)	SS	UNKNOWN	1 DAY
		OVERDOSE	
		AMOUNT	
Ethanol (Ethanol)	SS	UNKNOWN	1 DAY
		ORAL	OVERDOSE
		AMOUNT	
		UNKNOWN	
Temazepam		ORAL	1 DAY

(Temazepam) SS

OVERDOSE  
AMOUNT  
UNKNOWN 1 DAY

Date:11/03/99ISR Number: 3388694-3Report Type:Expedited (15-DaCompany Report #HQ3504525OCT1999

Age:18 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Convulsion Hyperglycaemia Hypoglycaemia Loss Of Consciousness Overdose Respiratory Arrest	Health Professional	Efexor (Venlafaxine Hydrochloride)	PS		ORAL	3675 MG	
			Cannabis (Cannabis)	SS		(OVERDOSE AMOUNT)		
			Co-Proxamol (Dextropropoxyphene Hydrochloride, Paracetamol)	SS		ORAL	100 COUNT	
			Codeine (Codeine)	SS		(OVERDOSE AMOUNT)		
			Ibuprofen (Ibuprofen)	SS		ORAL	(OVERDOSE AMOUNT)	
			Mebeverine (Mebeverine)	SS		ORAL	2025 MG	

Date:02/14/00ISR Number: 3459615-XReport Type:Periodic Company Report #001-0945-990118

Age:18 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion Delusion Depression Suicide Attempt	Consumer Health Professional	Neurontin (Gabapentin)	PS		ORAL	900-1100 MG	
			Marijuana (Cannabis)	SS		(DAILY), PER ORAL		
			Unspecified Birth Control Pills	C				
			Prozac (Fluoxetine Hydrochloride)	C				

Date:04/06/00ISR Number: 3484575-5Report Type:Expedited (15-DaCompany Report #232846

Age: Gender:Unknown I/FU:I

Outcome	PT
Other	Complications Of Maternal Exposure To Therapeutic

21-Jul-2006 10:28 AM

Page: 5

Freedom Of Information (FOI) Report

Drugs  
Small For Dates Baby

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Literature Health Professional	Saquinavir (Saquinavir Mesylate)	PS				
	Stavudine (Stavudine)	SS				
	Lamivudine (Lamivudine)	SS				
	Nelfinavir (Nelfinavir)	SS				
	Delavirdine (Delavirdine Mesylate)	SS				
	Marijuana (Cannabis)	SS				
	Zidovudine (Zidovudine)	SS				

Date:04/10/00ISR Number: 3485965-7Report Type:Expedited (15-DaCompany Report #232846

Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Complications Of Maternal Exposure To Therapeutic Drugs	Literature Health Professional	Saquinavir (Saquinavir Mesylate)	PS				
	Hepatitis C Medication Error		Stavudine (Stavudine)	SS				
	Pregnancy Induced Hypertension		Lamivudine (Lamivudine)	SS				
	Small For Dates Baby		Nelfinavir (Nelfinavir)	SS				
			Marijuana (Cannabis)	SS				
			Zidovudine (Zidovudine)	SS				

Date:04/14/00ISR Number: 3488708-6Report Type:Expedited (15-DaCompany Report #2000017006US

Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Intentional Overdose Suicide Attempt	Health Professional	Xanax (Alprazolam) Tablet	PS		ORAL	2 MG, SINGLE,	
			Tylenol Pm (Diphenhydramine, Paracetamol)	SS		ORAL	SINGLE, ORAL	
			Alcohol (Ethanol)	SS		ORAL	SINGLE, ORAL	1 DAY
			Marijuana (Cannabis)	SS			SINGLE	

Date:05/01/00ISR Number: 3495314-6Report Type:Expedited (15-DaCompany Report #S00-USA-00571-01

Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Health	Celexa (Citalopram Hydrobromide)	PS				
	Pulmonary Congestion	Professional	Clonazepam	SS				
	Pulmonary Oedema		Zolpidem	SS				
	Toxicologic Test Abnormal		Amitriptyline	SS				

21-Jul-2006 10:28 AM

Page: 6

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Mirtazepine SS  
 Quetiapine  
 (Quetiapine Fumarate) SS  
 Amphetamine SS  
 Cannabinoids SS  
 Ethanol SS

Date:06/05/00ISR Number: 3508579-9Report Type:Expedited (15-DaCompany Report #WAES 00056128

Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bronchitis	Foreign	Crixivan	PS	Merck Research Laboratories Div			
	Cardiovascular Disorder	Other			Merck Co Inc	ORAL	2400 MG PO	
	Chest Pain							
	Coronary Artery Disease		Cannabis	SS				
	Dyspnoea		Lamivudine	C				
	Echocardiogram Abnormal		Stavudine	C				
	Haemorrhoids							
	Tendonitis							

Date:06/08/00ISR Number: 3510703-9Report Type:Expedited (15-DaCompany Report #200311

Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Brain Oedema		Dhc Plus	PS	Purdue Frederick Co			
	Cardiac Failure		Heroin	SS				
	Circulatory Collapse		Cannabis	SS				
	Drug Abuser							
	Hepatitis C							
	Psychomotor Hyperactivity							
	Pulmonary Oedema							
	Pyrexia							
	Toxicologic Test Abnormal							

Date:08/08/00ISR Number: 3545404-4Report Type:Expedited (15-DaCompany Report #2000COU0333

Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Abuser	Health	Coumadin	PS	Dupont Merck Pharmaceutical Co	ORAL		
	International Normalised	Professional					4-16 MG DLY	



Ratio Decreased

Marijuana(Cannabis)	SS		PO
Ni (Baclofen)	C	ORAL	PO
Dulcolax (Bisacodyl)	C		
Amitriptyline			
(Amitriptyline)	C		
Ni (Oxybutynin)	C		

Date:09/15/00ISR Number: 3572607-5Report Type:Expedited (15-DaCompany Report #JRFUSA2000004531

Age:46 YR Gender:Female I/FU:F

Outcome  
Death  
Hospitalization -  
Initial or Prolonged  
Required

21-Jul-2006 10:28 AM

Page: 7

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Intervention to  
Prevent Permanent  
Impairment/Damage

PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Activated Partial Thromboplastin Time Prolonged	Literature Health Professional	Duragesic Paroxetine (Paroxetine)	PS	Alza Corp	TRANSDERMAL		TRANSD
Atrial Fibrillation		Acetaminophen	SS		ORAL	ORAL	
Blood Bicarbonate Decreased		W/Hydrocodone (Vicodin)	SS		ORAL	ORAL	
Blood Ph Decreased		Cannabis (Cannabis)	SS		UNKNOWN		UNKNOWN
Cardiac Arrest		Benzodiazepines					
Coma		(Benzodiazepine Derivatives)	SS		UNKNOWN		UNKNOWN
Completed Suicide							
Cyanosis							
Electrocardiogram St Segment Depression							
Hepatic Enzyme Increased							
Hypotension							
Po2 Decreased							
Prothrombin Time Prolonged							
Pupil Fixed							
Tachycardia							
Toxicologic Test Abnormal							

Date:10/03/00ISR Number: 3586136-6Report Type:Periodic Company Report #1999001349US

Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Lethargy Overdose	Health Professional	Xanax	PS	Pharmacia And Upjohn Co	ORAL	ORAL	
		Celebrex (Celecoxib)	SS		ORAL	1400MG SINGLE		

ORAL

Marijuana (Cannabis) SS  
 Cocaine (Cocaine) SS  
 Aspirin "Bayer"  
 (Acetylsalicylic  
 Acid) SS ORAL ORAL  
 Tylenol  
 (Paracetamol) SS ORAL ORAL

Date:10/16/00ISR Number: 3596078-8Report Type:Expedited (15-DaCompany Report #WAES 00056128 Age:46 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bronchitis Cardiac Disorder	Foreign Other	Crixivan	PS	Merck Research Laboratories Div			
	Chest Pain			Merck Co Inc	ORAL	2400 MG PO		
	Coronary Artery Disease		Cannabis	SS				
	Dyspnoea		Lamivudine	C				
	Haemorrhoids		Stavudine	C				
	Tendonitis							

21-Jul-2006 10:28 AM

Page: 8

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/16/00ISR Number: 3612917-6Report Type:Expedited (15-DaCompany Report #JRFUSA2000008908 Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose Toxicologic Test Abnormal	Consumer	Duragesic	PS	Alza Corp	TRANSDERMAL	100 MCG/H, 1	
						IN 72 HOUR		
						(S) TRANSD		
			Ambien (Zolpidem Tartrate)	SS		ORAL	ORAL	
			Amitriptyline (Amitriptyline)	SS		ORAL	ORAL	
			Diazepam (Diazepam)	SS		ORAL	ORAL	
			Methadone (Methadone)	SS		ORAL	ORAL	
			Carisoprodol (Carisoprodol)	SS		ORAL	ORAL	
			Darvocet (Darvocet)	SS		ORAL	ORAL	
			Thc (Cannabis)	SS				

Date:11/24/00ISR Number: 3617304-2Report Type:Expedited (15-DaCompany Report #2000SUS0872

Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Drug Abuser Drug Toxicity	Foreign Health Professional Other	Sustiva Alcohol (Ethanol) Amphetamine(S) Unspecified Cannabis Benzodiazepine - Unspecified Videx (Didanosine) Zerit (Stavudine)	PS	Dupont Pharmaceuticals Co	ORAL	600 MG QD PO	

Date:11/30/00ISR Number: 3627536-5Report Type:Periodic Company Report #A0123216A Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion Drug Interaction	Health Professional Company Representative	Wellbutrin Sr Cannabis (Formulation Unknown) (Cannabis)	PS	Glaxo Wellcome Inc	ORAL	ORAL	

Date:12/01/00ISR Number: 3621276-4Report Type:Expedited (15-DaCompany Report #2000-FF-S0642 Age: Gender:Male I/FU:F

Outcome PT  
Hospitalization - Blood Creatine  
Initial or Prolonged Phosphokinase Increased  
Blood Lactic Acid  
Increased  
Caesarean Section  
Complications Of Maternal  
Exposure To Therapeutic  
Drugs  
Drug Withdrawal Syndrome  
Neonatal  
Hyperkalaemia  
Hypertriglyceridaemia

21-Jul-2006 10:28 AM

Page: 9

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Macrocytosis  
Neonatal Disorder

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Neutropenia Neonatal Pregnancy		Foreign Other	Viramune	PS	Boehringer Ingelheim	ORAL	SEE B.5/PO	1 DAY
			Epivir	SS	Pharmaceuticals Inc	INTRA-UTERINE	IU/WHOLE	
			Zerit	SS	Pharmaceuticals Inc	INTRA-UTERINE	IU/WHOLE	
			Methadone	SS	Pharmaceuticals Inc	INTRA-UTERINE	20 MG/IU/WHOLE	

PREGNANCY

Bactrim	SS	
Cannabis	SS	INTRA-UTERINE IU/WHOLE PREGNANCY
Viracept	SS	INTRA-UTERINE IU/WHOLE PREGNANCY
Retrovir	C	

Date:12/15/00ISR Number: 3632205-1Report Type:Expedited (15-DaCompany Report #WAES 00127254 Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dysphoria Stupor Suicide Attempt	Foreign Other	Vasotec	PS	Merck Research Laboratories Div Merck Co Inc	ORAL	500 MG PO	
			Amphetamine	SS				
			Cannabis	SS				
			Insulin Lispro	SS				

Date:12/19/00ISR Number: 3632694-2Report Type:Expedited (15-DaCompany Report #250772 Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Delirium Drug Abuser		Roaccutane Cannabis	PS SS	Roche		32 DAY	
						THE PATIENT		
						SMOKED 5-6 CANNABIS CIGARETTES A DAY.		

Date:12/20/00ISR Number: 3634742-2Report Type:Expedited (15-DaCompany Report #250772 Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Delirium	Foreign Health Professional	Accutane Cannabis (Cannabis)	PS SS	Hlr Technology	ORAL ORAL RESPIRATORY (INHALATION) INHALATION	40 MG DAILY	

Date:12/21/00ISR Number: 3635642-4Report Type:Expedited (15-DaCompany Report #A034790 Age:51 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anxiety Drug Interaction Panic Attack	Foreign Health Professional	Viagra	PS Div	Pfizer Agricultural	ORAL	50.00 MG TOTAL: PRN:	

21-Jul-2006 10:28 AM

Page: 10

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

ORAL

Clopidogrel	SS	ORAL	75.00 MG
		TOTAL: DAILY:	
		ORAL	
Cannabis	SS	INHALATION	
Simvastatin	C		

Date:02/02/01ISR Number: 3658989-4Report Type:Expedited (15-DaCompany Report #A0138368A Age:15 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Condition Aggravated		Wellbutrin	PS	Glaxo Wellcome	ORAL per day	100MG 6 MON	Twice
	Drug Abuser		Marijuana	SS				
	Drug Interaction		No Concurrent Medications	C				
	Glycosuria							
	Syncope							

Date:02/05/01ISR Number: 3661279-7Report Type:Expedited (15-DaCompany Report #A0138368A Age:15 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated Disturbance In Social Behaviour	Health Professional	Wellbutrin Sr	PS	Glaxo Wellcome Inc	ORAL TWICER PER DAY / ORAL	100 MG /	
	Drug Interaction		Cannabis	SS				
	Movement Disorder							
	Syncope							

Date:02/06/01ISR Number: 3662121-0Report Type:Periodic Company Report #232695 Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hepatitis C Hypertension	Literature Health Professional	Saquinavir (Saquinavir Mesylate)	PS				
			Stavudine (Stavudine)	SS				
			Lamivudine (Lamivudine)	SS				
			Nelfinavir (Nelfinavir)	SS				
			Zidovudine (Zidovudine)	SS				
			Delavirdine (Delavirdine Mesylate)	SS				
			Marijuana (Cannabis)	SS				

Date:03/01/01ISR Number: 3671689-XReport Type:Expedited (15-DaCompany Report #A0138368A Age:15 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Condition Aggravated Disturbance In Social

Other Behaviour  
Drug Interaction  
Glycosuria

21-Jul-2006 10:28 AM

Page: 11

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Movement Disorder  
Syncope

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Health Professional	Wellbutrin	PS	Glaxo Wellcome	ORAL	100MG Twice	
	Marijuana	SS		per day	6 MON	
	Benadryl	C		ORAL	25MG As	
				required		

Date:03/05/01ISR Number: 3674046-5Report Type:Expedited (15-DaCompany Report #A0138368A Age:15 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required	Abnormal Behaviour Drug Dependence Drug Interaction	Health Professional	Wellbutrin Sr	PS	Glaxo Wellcome Inc	ORAL	100 MG /TWICE	
Intervention to Prevent Permanent Impairment/Damage	Drug Dependence Glycosuria Movement Disorder Syncope		Cannabis (Cannabis) Diphenhydramine Hcl	SS C		PER DAY /ORAL		

Date:03/29/01ISR Number: 3692517-2Report Type:Expedited (15-DaCompany Report #01-0459 Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aggression Blood Alcohol Increased Condition Aggravated Drug Ineffective Head Injury Pulmonary Embolism	Foreign Health Professional Company Representative	Loxitane Im Alcohol (Ethanol) Bromazepam Lysanxia (Prazepam)	PS SS SS SS	Watson Laboratories Inc	INTRAMUSCULAR ORAL	50 MG 1 X PER 1 DAY, IM 1 DAY ORAL ORAL 1 DAY 40 MG 1 X PER	
		Marijuana (Cannabis) Netux (Codeine/Phenyltoloxamine) Rivotril (Clonazepam) Solian (Amisulpride)	SS SS SS SS			RECTAL INHALATION ONE VIAL 1 DAY 400 MG 1 X PER 1 DAY,		
		Teralithe (Lithium Carbonate)	SS			ORAL	400 MG 3 X PER 1 DAY, ORAL	
		Tercian (Cyamemazine)	SS				ONE VIAL 1 DAY	

Date:04/30/01ISR Number: 3715011-9Report Type:Expedited (15-DaCompany Report #01-0459 FOLLOW-UP

Age:29 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abnormal Behaviour	Foreign	Loxitane Im	PS	Watson Laboratories			
	Aggression	Health	Inc			INTRAMUSCULAR	50 MG 1 X PER	
	Agitation	Professional				1 DAY, IM	1 DAY	
	Alcoholism	Company	Alcohol (Ethanol)	SS		ORAL	ORAL	1 DAY
	Drug Abuser	Representative	Bromazepam					
	Drug Ineffective		(Bromazepam)	SS				
	Head Injury		Lysanxia (Prazepam)	SS			40 MG 1 X PER	
	Toxicologic Test Abnormal						1 DAY	

21-Jul-2006 10:28 AM

Page: 12

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Marijuana (Cannabis)	SS	RESPIRATORY (INHALATION)	INHALATION	1 DAY
Netux (Codeine/Phenyltolox amine)	SS			
Rivotril (Clonazepam)	SS		ONE VIAL	1 DAY
Solian (Amisulpride)	SS		400 MG 1 X PER 1 DAY,	
Teralithe (Lithium Carbonate)	SS	ORAL	400 MG 3 X PER 1 DAY, ORAL	
Tercian (Cyamemazine)	SS		ONE VIAL	1 DAY

Date:05/02/01ISR Number: 3714608-XReport Type:Expedited (15-DaCompany Report #200104-1012(0)

Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Consumer	Pseudoephedrine -					
	Drug Level Above Therapeutic		Formulation Unspecified					
			(Pseudoephedrine)	PS		ORAL	PER ORAL	
			Alcohol (Ehtanol)	SS		ORAL	PER ORAL	
			Marijuana (Cannabis)	SS		RESPIRATORY (INHALATION)	INHALATION	
			Nasal Spray Nos	C				

Date:05/22/01ISR Number: 3727265-3Report Type:Expedited (15-DaCompany Report #HQ0944316MAY2001

Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Agitation	Health	Artane	PS	Lederle Laboratories			

Initial or Prolonged	Confusional State	Professional	Div American
	Coordination Abnormal	Other	Cyanamid Co
	Delirium	Marijuana (Cannabis,	
	Hallucinations, Mixed	)	SS
	Mydriasis	Unspecified	
	Toxicologic Test Abnormal	Benzodiazepine	
		(Unspecified	
		Benzodiazepine,	
		Unspec)	SS

Date:05/30/01ISR Number: 3730731-8Report Type:Expedited (15-DaCompany Report #01P-167-0106949-00 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Dizziness	Foreign	Depakote	PS	Abbott Laboratories	ORAL		SEE IMAGE
Initial or Prolonged	Hypotension	Health	Cannabis (Cannabis)	SS		RESPIRATORY		
	Palpitations	Professional				(INHALATION) INHALATION		
	Panic Disorder		Zuclopenthixol					
	Skin Discolouration		(Zuclopenthixol)	SS		SUBCUTANEOUS	SUBCUTANEOUS	
			Lorazepam					
			(Lorazepam)	C				

21-Jul-2006 10:28 AM

Page: 13

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/29/01ISR Number: 3750702-5Report Type:Expedited (15-DaCompany Report #2013170 Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Health	Morphine Sulfate	PS				
	Toxicologic Test Abnormal	Professional	Oxycodone					
	Other		Hydrochloride	SS				
			Quinine Sulfate	SS				
			Acetaminophen	SS				
			Cocaine	SS				
			Benzodiazepine	SS				
			Cannabinoids	SS				

Date:06/29/01ISR Number: 3750708-6Report Type:Expedited (15-DaCompany Report #2012671 Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Brain Oedema	Health	Morphine Sulfate	PS	Ab Generics Lp			
	Cardiomegaly	Professional	Opiates	SS				
	Drug Level Above	Other	Nicotine	SS				
	Therapeutic		Caffeine	SS				
	Eyelid Oedema		Cannabinoids	SS				
	Hepatic Steatosis		Benzodiazepines	SS				
	Hepatomegaly							
	Pulmonary Congestion							



Pulmonary Oedema  
Toxicologic Test Abnormal

Date:06/29/01ISR Number: 3750719-0Report Type:Expedited (15-DaCompany Report #2012670

Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Brain Oedema	Health	Morphine Sulfate					
	Cardiomegaly	Professional	(Similar To Nda					
	Coma	Other	19-516)	PS				
	Drug Level Above		Opiates	SS				
	Therapeutic		Nicotine	SS				
	Eyelid Oedema		Caffeine	SS				
	Hepatic Steatosis		Cannabinoids	SS				
	Hepatomegaly		Benzodiazepines	SS				
	Hypertension							
	Nervous System Disorder							
	Pulmonary Congestion							
	Pulmonary Oedema							

Date:07/10/01ISR Number: 3755900-2Report Type:Expedited (15-DaCompany Report #2013299

Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Toxicity	Health	Ms Contin	PS	Purdue Frederick Co			
	Toxicologic Test Abnormal	Professional	Propoxyphene Hcl	SS				
		Other	Codeine	SS				
			Cocaine	SS				
			Cannabinoids	SS				
			Ethanol (Alcohol, Anhydrous)	SS				

21-Jul-2006 10:28 AM

Page: 14

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/09/01ISR Number: 3774490-1Report Type:Expedited (15-DaCompany Report #2013732

Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Brain Oedema	Other	Morphine					
	Coma		Sulfate(Similar To					
	Drug Toxicity		Andas 74-769 And					
	Overdose		74-862)	PS	Abg Laboratories			
	Pulmonary Congestion		Diazepam	SS				
	Pulmonary Oedema		Alprazolam	SS				
	Toxicologic Test Abnormal		Hydromorphone Hcl	SS				
			Oxazepam	SS				
			Temazepam	SS				
			Acetaminophen	SS				
			Hydrocodone					

Bitartrate SS  
Cannabinoids SS

Date:09/19/01ISR Number: 3796445-3Report Type:Expedited (15-DaCompany Report #2013796

Age:17 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Animal Bite	Health	Ms Contin Tablets 30					
	Excoriation	Professional	Mg Cr (Morphine Sulfate)	PS		ORAL	MG PO	
	Skull Fractured Base	Other	Amphetamine	SS				
	Toxicologic Test Abnormal		Methadone	SS				
			Cannabinoids	SS				
			Caffeine Anhydride	SS				
			Nicotine	SS				
			Diazepam	SS				

Date:09/27/01ISR Number: 3800736-7Report Type:Expedited (15-DaCompany Report #2001073680US

Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Amnesia	Other	Xanax					
	Cerebrovascular Accident		(Alprazolam)Tablet	PS		NASAL	NASAL	
	Confusional State		Marijuana (Cannabis	SS		NASAL	NASAL	1 DAY
Other	Gait Disturbance							
	Medication Error							
	Sluggishness							
	Speech Disorder							
	Vomiting							

Date:10/01/01ISR Number: 3802645-6Report Type:Expedited (15-DaCompany Report #PHBS2001NZ08935

Age:28 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Foreign	Clozaril (Clozapine)					
	Medication Error	Health	Tablet	PS		ORAL	300 MG/D,	
	Social Avoidant Behaviour	Professional					ORAL; 325	
	Thought Withdrawal	Other					MG/D, ORAL	
	Weight Increased		Cannabis (Cannabis)	SS				

21-Jul-2006 10:28 AM

Page: 15

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/03/01ISR Number: 3804333-9Report Type:Expedited (15-DaCompany Report #2014348

Age:16 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
---------	----	---------------	---------	------	--------------	-------	------	----------

Death	Completed Suicide	Health	Oxycodone	
	Drug Toxicity	Professional	Hydrochloride	PS
		Other	Hydrocodone	
			Bitartrate	SS
			Cannabinoids	SS
			Methadone	SS
			Carisoprodol	SS
			Butalbital	SS
			Alcohol	SS
			Benzodiazepines	SS

Date:10/03/01ISR Number: 3806060-0Report Type:Expedited (15-DaCompany Report #2014347

Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Road Traffic Accident	Health	Oxycodone					
		Professional	Hydrochloride	PS				
		Other	Hydrocodone					
			Bitartrate	SS				
			Amobarbital	SS				
			Pentobarbital	SS				
			Phenobarbital	SS				
			Secobarbital	SS				
			Chlordiazepoxide	SS				
			Diazepam	SS				
			Oxazepam	SS				
			Cannabinoids	SS				
			Cocaine	SS				
			Codeine	SS				
			Hydromorphone	SS				
			Meperidine	SS				
			Methadone	SS				
			Morphine	SS				
			Pentazocine	SS				
			Propoxyphene	SS				
			Methaqualone	SS				

Date:12/26/01ISR Number: 3844939-4Report Type:Expedited (15-DaCompany Report #01P-056-0113943-00

Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Level Above Therapeutic	Foreign	Tranxene Tablets					
	Intentional Overdose	Health	(Tranxene )					
		Professional	(Clorazepate					
		Other	Dipotassium)					
			(Clorazepate	PS		ORAL	PER ORAL	
			Oxazepam	SS		ORAL	PER ORAL	
			Bromazepam	SS		ORAL	PER ORAL	
			Diazepam	SS		ORAL	PER ORAL	
			Ethanol	SS				
			Cocaine	SS				
			Cannabis	SS				

## FDA - Adverse Event Reporting System (AERS)

## Freedom Of Information (FOI) Report

Date:12/26/01ISR Number: 3845275-2Report Type:Expedited (15-DaCompany Report #HQ9470313DEC2001

Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Foreign	Seresta (Oxazepam, Tablet)	PS		ORAL	ORAL	1 DAY
	Toxicologic Test Abnormal	Health	Alcohol (Ethanol)	SS			1 DAY	
	Professional	Other	Cocaine (Cocaine)	SS			1 DAY	
			Lexomil (Bromazepam)	SS			1 DAY	
			Marijuana (Cannabis)	SS			1 DAY	
			Tranxene (Clorazepate Dipotassium)	SS		1 DAY		
			Valium (Diazepam)	SS		1 DAY		

Date:01/10/02ISR Number: 3850977-8Report Type:Expedited (15-DaCompany Report #2015458

Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Brain Oedema	Health	Oxycodone Hydrochloride	PS				
	Cerebral Arteriosclerosis	Professional	Propoxyphene Hcl	SS				
	Drug Toxicity	Other	Naproxen	SS				
	Nephrosclerosis		Lidocaine Hcl	SS				
	Pulmonary Oedema		Nicotine	SS				
	Toxicologic Test Abnormal		Alprazolam	SS				
	Ventricular Hypertrophy		Valproic Acid	SS				
			Caffeine	SS				
			Cannabinoids	SS				

Date:01/31/02ISR Number: 3862963-2Report Type:Expedited (15-DaCompany Report #2014978

Age:18 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Failure	Foreign	Oxycodone Hydrochloride	PS				
	Coma	Health	Valium (Diazepam)	SS		ORAL	PO	
	Overdose	Professional	Temazepam	SS		ORAL	PO	
	Pulmonary Congestion	Company	Citalopram	SS		ORAL	PO	
	Pulmonary Oedema	Representative	Cannabinoids	SS		ORAL	PO	
	Toxicologic Test Abnormal	Other						

Date:02/08/02ISR Number: 3867423-0Report Type:Expedited (15-DaCompany Report #HQ0496306FEB2002

Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Agitation Disorientation Drug Abuser	Health Professional	Parkinane Lp (Trihexyphenidyl, Capsule, Sustained					

Drug Interaction  
Hallucination, Visual  
Medication Error

Release) PS

ORAL 1 CAPSULE 1X  
PER 1 DAY  
ORAL 1 DAY

Cannabis (Cannabis,  
) SS  
Unspecified  
Benzodiazepine  
(Unspecified  
Benzodiazepine,  
Unspec) SS

21-Jul-2006 10:28 AM

Page: 17

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/08/02ISR Number: 3868272-XReport Type:Expedited (15-DaCompany Report #HQ0496306FEB2002 Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Agitation Disorientation Drug Abuser Drug Interaction Hallucination, Visual	Foreign Health Professional Other	Parkinane Lp (Trihexyphenidyl, Capsule, Sustained Release)	PS		ORAL	1 CAPSULE 1X PER 1 DAY 1 DAY	
			Cannabis (Cannabis) Unspecified Benzodiazepine (Unspecified Benzodiazepine, Unspec)	SS				

Date:02/13/02ISR Number: 3869394-XReport Type:Periodic Company Report #2013270 Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-553)	PS				
			Ethanol (Alcohol, Anhydrous) Cocaine Cannabinoids Carisoprodol Meprobamate	SS SS SS SS SS				

Date:02/13/02ISR Number: 3869464-6Report Type:Periodic Company Report #2012183 Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health Professional Other	Oxycodone Hydrochloride (Similar To Nda					

20-553) PS  
Ethanol SS  
Cannabinoids SS

Date:02/13/02ISR Number: 3869466-XReport Type:Periodic Company Report #2013192 Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda					
			20-553) PS					
			Ethanol SS					
			Cannabinoids SS					

21-Jul-2006 10:28 AM

Page: 18

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/13/02ISR Number: 3869571-8Report Type:Periodic Company Report #2012425 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda					
			20-553) PS					
			Fluoxetine					
			Hydrochloride SS					
			Diphen					
			(Diphenhydramine					
			Hcl) SS					
			Cannabinoids SS					
			Acetaminophen SS					

Date:02/13/02ISR Number: 3869593-7Report Type:Periodic Company Report #2012335 Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda					
			20-553) PS					
			Hydromorphone					
			Hydrochloride SS					
			Sertraline SS					
			Alprazolam SS					

Cannabiods SS  
 Temazepam SS  
 Acetaminophen SS  
 Trazadone SS  
 Lidocaine Hcl SS

Date:02/13/02ISR Number: 3870579-7Report Type:Periodic Company Report #2012574 Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda					
			20-553)	PS				
			Cocaine	SS				
			Diazepam	SS				
			Oxazepam	SS				
			Cannabinoid	SS				

Date:02/13/02ISR Number: 3870582-7Report Type:Periodic Company Report #2012642 Age:51 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda					
			20-553)	PS				
			Diphenhydramine	SS				
			Caffeine	SS				
			Nicotine	SS				
			Methocarbamol	SS				

21-Jul-2006 10:28 AM

Page: 19

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Alprazolam SS  
 Ethanol SS  
 Cannabinoids SS  
 Neurontin  
 (Gabapentin) C  
 Paxil (Paroxetine) C  
 Mirtazapine C  
 Diazepam C  
 Divalproex Sodium C  
 Dicyclomine Hcl C  
 Dilantin (Phenytoin) C  
 Lansoprazole C  
 Docusate Sodium C  
 Calcium Carbonate C  
 Cyanobalamin C

Date:02/13/02ISR Number: 3870583-9Report Type:Periodic Company Report #2012643 Age:26 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda					
			20-553)	PS				
			Cannabinoids	SS				
			Caffeine	SS				
			Ethanol	SS				
			Benzodiazepine	SS				
			D-Lysergic	SS				
			Diethylamide	SS				

Date:02/13/02ISR Number: 3870592-XReport Type:Periodic Company Report #2012566 Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agitation	Health	Oxycontin Cr					
Other	Overdose	Professional	Tablets, 40 Mg					
		Other	(Oxycodone					
			Hydrochloride)	PS	ORAL	40 MG BID PO		
			Oxycontin Cr					
			Tablets, 80 Mg					
			(Oxycodone					
			Hydrochloride)	SS	ORAL	80 MG Q12H PO		
			Oxyir Capsules					
			(Oxycodone					
			Hydrochloride)	SS	ORAL	20 MG Q12H		
					PRN PO			
			Roxicodone					
			(Oxycodone)	SS	ORAL	30 MG Q6H PRN		
					PO			
			Alprazolam	SS	ORAL	2 MG Q6H PRN		
					PO			
			Cannabinoids	SS				
			Nicotine	SS				
			Lidocaine	SS				
			Hydrocodone					
			Bitartrate	SS				
			Paxil (Paroxetine)	C				

21-Jul-2006 10:28 AM

Page: 20

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/13/02ISR Number: 3870597-9Report Type:Periodic Company Report #2012572 Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
		Professional	Hydrochloride	PS				
		Other	Cannabinoid	SS				



Date:02/13/02ISR Number: 3870602-XReport Type:Periodic Company Report #2013433

Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycontin Cr Tablets	PS		ORAL	MG	PO
		Professional	Hydrocodone					
		Other	Bitartrate	SS				
			Diazepam	SS				
			Propoxyphene Hcl	SS				
			Acetaminophen	SS				
			Oxazepam	SS				
			Temazepam	SS				
			Caffeine Anhydride	SS				
			Nicotine	SS				
			Cannabinoids	SS				

Date:02/13/02ISR Number: 3870632-8Report Type:Periodic Company Report #2012264

Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda					
			20-553)	PS				
			Hydrocodone					
			Bitartrate	SS				
			Ethyl Alcohol	SS				
			Cocaine	SS				
			Diazepam	SS				
			Cannabinoids	SS				
			Oxazepam	SS				
			Acetaminophen	SS				

Date:02/13/02ISR Number: 3870634-1Report Type:Periodic Company Report #2012266

Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda					
			20-553)	PS				
			Diazepam	SS				
			Methadone	SS				
			Cocaine	SS				
			Amitriptyline	SS				
			Chlordiazepoxide	SS				
			Oxazepam	SS				
			Cannabinoids	SS				
			Temazepam	SS				
			Lidocaine Hcl	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/13/02ISR Number: 3870636-5Report Type:Periodic Company Report #2012268 Age:46 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-553)					
			PS					
			Hydrocodone Bitartrate					SS
			Alprazolam					SS
			Cocaine					SS
			Cannabinoids					SS
			Lidocaine					SS
			Lorazepam					SS
			Acetaminophen					SS

Date:02/13/02ISR Number: 3871085-6Report Type:Periodic Company Report #2015032 Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health Professional Other	Oxycontin Cr Tablets, 20 Mg (Oxycodone Hydrochloride)					
			PS			20 MG PO		
			Cannabinoids					SS
			Nicotine					SS
			Caffeine Anhydride					SS
			Atropine					SS

Date:02/13/02ISR Number: 3872410-2Report Type:Periodic Company Report #2014837 Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-553)					
			PS					
			Hydromorphone					SS
			Promethazine					SS
			Cannabinoids					SS

Date:02/13/02ISR Number: 3873170-1Report Type:Periodic Company Report #2012065 Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health Professional Other	Oxycontin Cr Tablets, 80 Mg (Oxycodone Hydrochloride)					
			PS			ORAL		
			Ethanol (Alcohol,			PO		

Anhydrous)	SS	ORAL	PO
Diazepam	SS	ORAL	PO
Temazepam	SS	ORAL	PO
Carisoprodol	SS	ORAL	PO
Meprobamate	SS	ORAL	PO
Cannabinoids	SS		

21-Jul-2006 10:28 AM

Page: 22

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/13/02ISR Number: 3873176-2Report Type:Periodic Company Report #2012650 Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda					
			20-553)	PS				
			Cannabinoids	SS				
			Nicotine	SS				
			Caffeine Anhydride	SS				
			Ethanol	SS				

Date:02/13/02ISR Number: 3873201-9Report Type:Periodic Company Report #2014225 Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Consumer	Oxycodone					
Other	Apnoea	Other	Hydrochloride	PS		NASAL	MG UNKNOWN	
	Drug Dependence					NOSE		
			Alcohol	SS				
			Cannabinoids	SS				

Date:02/13/02ISR Number: 3875455-1Report Type:Periodic Company Report #2012979 Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Intentional Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda					
			20-553)	PS				
			Hydrocodone					
			Bitartrate	SS				
			Acetaminophen	SS				
			Cannabinoids	SS				

Date:02/13/02ISR Number: 3875459-9Report Type:Periodic Company Report #2012968 Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
---------	----	---------------	---------	------	--------------	-------	------	----------



Alprazolam SS  
Cannabinoids SS  
Atropine SS

Date:02/13/02ISR Number: 3876158-XReport Type:Periodic Company Report #2010782 Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	(Oxycodone					
		Professional	Hydrochloride)					
		Other	(Similar To Nda					
			20-553)	PS				
			Heroin	SS				
			Xanax (Alprazolam)	SS				
			Cocaine	SS				
			Cannabinoids	SS				
			Hydrocodone	SS				
			Propoxyphene Hcl	SS				
			Acetaminophen	SS				

Date:02/13/02ISR Number: 3876252-3Report Type:Periodic Company Report #2012529 Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda					
			20-553)	PS				

21-Jul-2006 10:28 AM

Page: 24

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Diazepam SS  
Temazepam SS  
Acetaminophen SS  
Fluoxetine  
Hydrochloride SS  
Cannabinoids SS

Date:02/13/02ISR Number: 3876278-XReport Type:Periodic Company Report #2013067 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda					
			20-553)	PS				
			Thioridazine	SS				
			Cannabinoids	SS				

Date:02/13/02ISR Number: 3876680-6Report Type:Periodic Company Report #2012160 Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	Diazepam					
			Cannabinoids			MG		
			Citalopram			MG		
			Diphenhydramine Hcl			MG		
			Dimenhydrinate			MG		
			Caffeine Anhydride					

Date:02/13/02ISR Number: 3876715-0Report Type:Periodic Company Report #2013976 Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda					
			20-553)					
			Diazepam					
			Meprobamate					
			Cocaine					
			Atropine					
			Cannabinoids					

Date:02/13/02ISR Number: 3876722-8Report Type:Periodic Company Report #2013951 Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda					
			20-553)					
			Acetaminophen			ORAL		
			Cannabinoids			MG		
			Alcohol			PO		

21-Jul-2006 10:28 AM

Page: 25

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/13/02ISR Number: 3876727-7Report Type:Periodic Company Report #2013968 Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycontin Cr					
		Professional	Tablets, 40 Mg					
		Other	(Oxycodone					
			Hydrochloride)					
			Propoxyphene					
			Cannabinoids					

Date:02/13/02ISR Number: 3876777-0Report Type:Periodic Company Report #2012202 Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda					
			20-553)					
			PS					
			Promethazine				SS	
			Diazepam				SS	
			Methylene					
			Dioxymethamphetamine				SS	
			Cannabinoids				SS	
			Ethanol (Alcohol,					
			Anhydrous)				SS	

Date:02/13/02ISR Number: 3876795-2Report Type:Periodic Company Report #2012669 Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Intentional Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda					
			20-553)					
			PS					
			Hydrocodone					
			Bitartrate			MG		
			Dihydrocodeine					
			(Similar To Anda					
			88-584)			MG		
			SS					
			Tramadol					
			Hydrochloride		ORAL	MG PO		
			SS					
			Alprazolam			MG		
			SS					
			Propoxyphene Hcl			MG		
			SS					
			Ephedrine					
			SS					
			Pseudoephedrine Hcl					
			SS					
			Caffeine					
			SS					
			Cannabinoids					
			SS					
			Nicotine					
			SS					
			Acetaminophen					
			SS					

Date:02/13/02ISR Number: 3876802-7Report Type:Periodic Company Report #2012662 Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda					
			20-553)					
			PS					

Diazepam SS  
 Cocaine SS  
 Carisoprodol SS  
 Cannabinoids SS

Date:02/13/02ISR Number: 3877697-8Report Type:Periodic Company Report #2011135 Age:34 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Dependence	Consumer	Oxycontin Cr					
		Other	Tablets, 10 Mg (Oxycodone Hydrochloride)	PS		MG		
			Marihuana	SS				

Date:02/13/02ISR Number: 3877724-8Report Type:Periodic Company Report #2013092 Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose		Oxycodone Hydrochloride (Similar To Nds 20-553)	PS				
			Cannabinoids	SS				
			Diazepam	SS				
			Chlordiazepoxide	SS				
			Oxazepam	SS				
			Fentanyl	SS				
			Carisoprodol	SS				
			Meprobamate	SS				
			Ethynol (Alcohol, Anhydrous)	SS				

Date:02/13/02ISR Number: 3877739-XReport Type:Periodic Company Report #2013024 Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Health	Oxycontin Cr	PS		ORAL	10 MG	PO
		Professional	Oxycontin Cr					
		Other	Tablets, 20 Mg (Oxycodone Hydrochloride)	SS	ORAL	20 MG	PO	
			Doxepin Hcl	SS		10 MG		
			Cyclobenzaprine Hcl	SS		10 MG		
			Carisoprodol	SS		350 MG		
			Meprobamate	SS				
			Dextromethorphan	SS				
			Acetaminophen	SS				
			Cannabinoids	SS				
			Ephedrine	SS				
			Pseudoephedrine Hcl	SS				



FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/13/02ISR Number: 3877743-1Report Type:Periodic Company Report #2013033 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Health Professional	Oxycodone Hydrochloride	PS	ORAL	MG PO		
			Ethanol (Alcohol, Anhydrous)	SS				
			Acetaminophen	SS				
			Methadone	SS				
			Nordiazepam	SS				
			Cannabinoids	SS				
			Oxazepam	SS				
			Temazepam	SS				
			Promethazine Hcl	SS				

Date:02/13/02ISR Number: 3877751-0Report Type:Periodic Company Report #2013034 Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Health Professional Other	Oxycontin Cr Tablets, 10 Mg (Oxycodone Hydrochloride)	PS				
			Ethanol (Alcohol, Anhydrous)	SS				
			Alprazolam	SS				
			Oxazepam	SS				
			Propoxyphene Hcl	SS				
			Cannabinoids	SS				

Date:02/13/02ISR Number: 3877767-4Report Type:Periodic Company Report #2013985 Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Health Professional	Oxycodone Hydrochloride	PS				
			Butalbital Compound	SS				
			Cannabinoids	SS				

Date:02/13/02ISR Number: 3878361-1Report Type:Periodic Company Report #2011723 Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Other	Oxycodone Hydrochloride (Similar To Nda 20-553)				PS	
			Carisoprodol				SS	
			Vicodin (Hydrocodone/Acetaminophen)				SS	
			Cocaine				SS	
			Acetaminophen				SS	
			Diphenhydramine Hcl				SS	
			Phenylpropanolamine Hcl				SS	
			Cannabinoids				SS	

21-Jul-2006 10:28 AM

Page: 28

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/13/02ISR Number: 3878817-1Report Type:Periodic Company Report #2010949 Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Consumer	Oxycodone Hydrochloride (Similar To Nda 20-553)				PS	
		Other	Methadone				SS	
			Cannabinoids				SS	
			Ranitidine				SS	
			Benzodiazepine				SS	

Date:02/13/02ISR Number: 3879481-8Report Type:Periodic Company Report #2012897 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Intentional Overdose	Health	Oxycodone Hydrochloride (Similar To Nda 20-553)				PS	
		Professional	Hydrocodone Bitartrate				SS	
		Other	Dihydrocodeine (Similar To Anda 88-584)				SS	
			Diphenhydramine Hcl				SS	
			Cannabinoids				SS	
			Alprazolam				SS	
			Diazepam				SS	

Date:03/01/02ISR Number: 3878566-XReport Type:Expedited (15-DaCompany Report #USA-2002-0000104

Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bronchopneumonia Drug Interaction Hepatic Steatosis Overdose Pulmonary Congestion	Health Professional Other	Morphine Sulfate (Similar To Andas 74-769 And 74-862) (Morphine Sulfate) Er Tablet					PS
			Morphine Sulfate (Similar To Nda 19-516) (Morphine Sulfate) Cr Tablet				SS	
			Ethanol (Ethanol)				SS	
			Diazepam (Diazepam)				SS	
			Marijuana (Cannabis)				SS	
			Desipramine (Desipramine)				SS	
			Cocaine (Cocaine)				SS	
			Nicotine (Nicotine)				SS	

Date:03/01/02ISR Number: 3878567-1Report Type:Expedited (15-DaCompany Report #USA-2002-0000102

Age:32 YR Gender:Male I/FU:I

Outcome  
Death

PT  
Atelectasis  
Completed Suicide  
Drug Level Above

21-Jul-2006 10:28 AM

Page: 29

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Therapeutic  
Intentional Overdose  
Lymphadenopathy

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Pulmonary Granuloma Pulmonary Oedema Toxicologic Test Abnormal		Health Professional Other	Similar To Andas 74-769 And 74-862) (Morphine Sulfate) Er Tablet					PS
			Oxycodone Hydrochloride (Similar To Nda 20-553) (Oxycodone Hydrochloride)				SS	
			Morphine Sulfate (Similar To Nda 19-516) (Morphine Sulfate) Cr Tablet				SS	
			Codeine (Codeine)				SS	
			Diazepam (Diazepam)				SS	
			Propoxyphene (Detropropoxyphene)				SS	
			Trimethorprim				SS	
			Marijuana (Cannabis)				SS	
			Erythromycin					

(Erythromycin) SS

Date:03/19/02ISR Number: 3885436-XReport Type:Expedited (15-DaCompany Report #A205728

Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Myocardial Infarction	Foreign Literature Health Professional	Viagra Tablets Cannabis	PS SS				

Date:04/12/02ISR Number: 3898882-5Report Type:Expedited (15-DaCompany Report #B0259974A

Age:19 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Brain Oedema Cerebral Infarction	Health Professional	Imigran Marijuana	PS SS	Glaxo Wellcome	SUBCUTANEOUS		
	Dysarthria Dysphagia Vasoconstriction Vertigo							

Date:04/24/02ISR Number: 3907396-5Report Type:Expedited (15-DaCompany Report #2013363

Age:34 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged Other Required Intervention to Prevent Permanent Impairment/Damage	Anxiety Arthralgia Bone Pain Cardiomegaly Chest Pain Chronic Obstructive Pulmonary Disease

21-Jul-2006 10:28 AM

Page: 30

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Coma	Delirium	Drug Dependence	Drug Toxicity	Dyspepsia	Dyspnoea	Erectile Dysfunction	Hypertonia	Hypoaesthesia	Joint Stiffness	Legal Problem	Muscular Weakness
		Report Source	Product	Role	Manufacturer	Route	Dose	Duration			
		Health	Oxycontin Tablets								
		Professional	(Oxycodone								
		Other	Hydrochloride) Cr								
			Tablet	PS		ORAL					
						ORAL					
			Amitriptyline								
			(Amitriptyline)	SS							
			Acetaminophen								
			(Paracetamol)	SS							

Nocturia	Cannabinoids ()	SS
Overdose	Tylox (Oxycodone	
Pain In Extremity	Terephthalate)	C
Paraesthesia	Ativan (Lorazepam)	C
Pollakiuria	Xanax (Alprazolam)	C
Stridor	Vioxx (Rofecoxib)	C
Toxicologic Test Abnormal	Pamelor	
Urinary Incontinence	(Nortriptyline	
Wheezing	Hydrochloride)	C
	Ultram	C
	Skelaxin	
	(Metaxalone)	C
	Buspar (Buspirone	
	Hydrochloride)	C
	Tenormin (Atenolol)	C
	Narcan (Naloxone	
	Hydrochloride)	C
	Ambien (Zolpidem	
	Tartrate)	C
	Haldol (Haloperidol)	C
	Cogentin	
	(Benzatropine	
	Mesilate)	C

Date:04/26/02ISR Number: 3908367-5Report Type:Expedited (15-DaCompany Report #PHRM2002FR01226

Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Foreign	Trileptal					
		Health	(Oxcarbazepine)					
		Professional	Tablet	PS		ORAL	900 MG/DAY	
		Company				ORAL		
		Representative	Nozinan					
		Other	(Levomepromazine)					
			Tablet	SS		ORAL	1 TO 2 DF/DAY	
						ORAL		
			Urbanyl (Clobazam)					
			Unknown	SS		ORAL	40 MG DAY	
						ORAL		
			Subutex					
			(Buprenorphine					
			Hydrochloride)					
			Tablet	SS		ORAL	ORAL	
			Lexomil (Bromazepam)					
			Tablet	SS		ORAL	ORAL	
			Cannabis(Cannabis)	SS		ORAL	ORAL	

21-Jul-2006 10:28 AM

Page: 31

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/01/02ISR Number: 3911238-1Report Type:Expedited (15-DaCompany Report #PHRM2002FR01226

Age:21 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Foreign Health Professional Company Representative	Trileptal(Oxcarbazepine) Tablet PS			ORAL	900 MG/DAY, ORAL	
		Nozinan (Levomepromazine) Tablet SS				ORAL	1 TO 2 DF/DAY, PRN, ORAL	
		Urbanyl (Clobazam) Tablet SS				ORAL	40 MG/DAY, ORAL	
		Subutex (Buprenorphine Hydrochloride) Tablet SS				ORAL	ORAL	
		Lexomil (Bromazepam) Tablet SS				ORAL	PRN, ORAL	
		Cannabis (Cannabis) SS						

Date:06/21/02ISR Number: 3938180-4Report Type:Expedited (15-DaCompany Report #USA-2002-0001349 Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Alcohol Increased	Health Professional	Oxycontin Tablets 20 Mg (Oxycodone Hydrochloride) Cr			ORAL	20 MG, QL2H, ORAL	
Hospitalization - Initial or Prolonged	Cerebellar Infarction Cyanosis		Cannabis(Cannabis) Tablet PS	SS			UNK MG, UNK, 6 DAY	
	Dizziness Drug Screen Positive Loss Of Consciousness Oxygen Saturation Decreased Prophylaxis Respiratory Disorder Somnolence		Alcohol(Ethanol) Benzodiazepin()	SS SS		ORAL ORAL	UNK L, UNK, 6 DAY UNK MG, UNK, 6 DAY	
		Prozac (Fluoxetine Hydrochloride) C						
		Klonopin (Clonazepam) C						
		Colace C						
		Zofran (Ondansetron Hydrochloride) C						

Date:07/02/02ISR Number: 3943810-7Report Type:Expedited (15-DaCompany Report #2013363 Age:34 YR Gender:Male I/FU:F

Outcome	PT
Death	Abnormal Behaviour
Hospitalization - Initial or Prolonged	Aggression Anxiety
Other	Arthralgia Back Pain Bone Pain Cardiomegaly Chest Pain Chronic Obstructive

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Adverse Event	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Delirium							
Disorientation							
Drug Dependence	Health	Oxycontin Tablets 20					
Drug Effect Decreased	Professional	Mg(Oxycodone					
Drug Toxicity	Other	Hydrochloride) Cr					
Dyspepsia		Tablet PS			ORAL	20 MG / ORAL	
Dyspnoea		Oxycontin Tablets					
Erectile Dysfunction		40mg (Oxycodone					
Hypertonia		Hydrochloride) Cr					
Hypoaesthesia		Tablet SS			ORAL	40 MG / ORAL	
Joint Stiffness		Hydrocodone /Apap					
Muscular Weakness		(Paracetamol,					
Mydriasis		Hydrocodone					
Nocturia		Bitartrate) SS			ORAL	10 MG, SEE	
Overdose					TEXT, ORAL		
Pain In Extremity		Cannabinoids ()	SS				1229 DAY
Paraesthesia		Acetaminophen					
Pollakiuria		(Paracetamol)	SS				1229 DAY
Pupillary Reflex Impaired		Amitriptyline					
Sexual Dysfunction		(Amitriptyline)	SS				1229 DAY
Somnolence		Tylox (Oxycodone					
Speech Disorder		Terephthalate) C					
Stridor		Ativan (Lorazepam)	C				
Toxicologic Test Abnormal		Xanax (Alprazolam)	C				
Urinary Incontinence		Vioxx (Rofecoxib)	C				
Vomiting		Pamelor					
Wheezing		(Nortriptyline					
		Hydrochloride)	C				
		Ultram	C				
		Skelaxin					
		(Metaxalone)	C				
		Buspar (Buspirone					
		Hydrochloride)	C				
		Tenormin (Atenlol)	C				
		Narcan (Naloxone					
		Hydrochloride)	C				
		Ambien (Zolpidem					
		Tartrate)	C				
		Haldol (Haloperidol)	C				
		Cogentin					
		(Benzatropine					
		Mesilate)	C				
		Narcan (Naloxone					
		Hydrochloride)	C				
		Diazepam (Diazepam)	C				
		Baclofen (Baclofen)	C				

Date:07/12/02ISR Number: 3948459-8Report Type:Expedited (15-DaCompany Report #USA-2002-0001513

Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Brain Oedema	Health	Oxycontin Tablets					
	Cardiac Failure	Professional	(Oxycodone					
	Congestive	Other	Hydrochloride) Cr					
	Cardiomegaly		Tablet PS		ORAL	ORAL		
	Drug Screen Positive		Hydrocodone					
	Pleural Effusion		Bitartrate (Similar					
	Pulmonary Oedema		To Ind 59, 175)					
			(Hydrocodone					

21-Jul-2006 10:28 AM

Page: 33

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Bitartrate) Unknown	SS	ORAL	ORAL
Methadone(Methadone)			
Unknown	SS	ORAL	ORAL
Amitriptyline(Amitri			
ptyline)Tablet	SS	ORAL	ORAL
Valium (Diazepam)			
Tablet	SS	ORAL	ORAL
Orphenadrine(Orphena			
dine) Tablet	SS	ORAL	ORAL
Marijuana(Cannabis)			
Unknown	SS		

Date:07/12/02ISR Number: 3948716-5Report Type:Expedited (15-DaCompany Report #A0373107A

Age:16 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Acute Psychosis	Foreign	Paxil (Formulation					
Other	Aggression	Literature	Unknown) (Paroxetine					
	Intentional Self-Injury	Consumer	Hydrochloride)	PS		ORAL	SEE DOSAGE	
	Psychiatric Symptom					TEXT/ORAL	6 MON	
	Suicide Attempt		Cannabis					
	Theft		(Formulation					
	Thinking Abnormal		Unknown) (Cannabis)	SS				
			Ethanol (Formulation					
			Unknown) (Alcohol)	SS				

Date:07/17/02ISR Number: 3951458-3Report Type:Expedited (15-DaCompany Report #2013363

Age:34 YR Gender:Male I/FU:F

Outcome	PT
Death	Accidental Overdose
Hospitalization -	Aggression
Initial or Prolonged	Arthralgia
Other	Bone Pain
	Bronchitis
	Cardiomegaly



Chest Pain  
 Chronic Obstructive  
 Pulmonary Disease  
 Coma  
 Cough  
 Delirium  
 Diarrhoea  
 Disorientation  
 Drug Toxicity  
 Drug Withdrawal Syndrome  
 Dyspepsia  
 Dyspnoea  
 Enuresis  
 Fall  
 Hypoaesthesia  
 Joint Stiffness  
 Muscular Weakness  
 Pain In Extremity  
 Paraesthesia  
 Pollakiuria  
 Pupillary Reflex Impaired  
 Pyrexia  
 Sexual Dysfunction  
 Somnolence

21-Jul-2006 10:28 AM

Page: 34

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Urinary Incontinence  
 Vomiting  
 Wheezing

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Health Professional Other	Oxycontin Oxycontin Tablets (Oxycodone Hydrochloride) Cr Tablet Hydrocodone/Apap (Paracetamol, Hydrocodone Bitartrate) Unknown	PS SS SS		ORAL ORAL ORAL	20 MG, ORAL 40 MG, ORAL 10 MG, SEE TEXT, ORAL	
	Amitriptyline (Amitriptyline) Acetaminophen (Paracetamol) Cannabinoids Xanax (Alprazolam) Vioxx (Rofecoxib) Pamelor (Nortriptyline Hydrochloride) Ultram Skelaxin (Metaxalone)	SS SS SS C C C C			100 MG, NOCTE 1229 DAY 1229 DAY 1229 DAY	1229 DAY 1229 DAY

Buspar (Buspirone Hydrochloride) C  
 Tenormin (Atenolol) C  
 Narcan C  
 Ambien (Zolpidem Tartrate) C  
 Haldol (Haloperidol) C  
 Cogentin (Benzatropine Mesilate) C  
 Narcan C  
 Diazepam (Diazepam) C  
 Baclofen (Baclofen) C  
 Lorcet C  
 Toradol (Ketorolac Tromethamine) C  
 Phenergan (Promethazine Hydrochloride) C  
 E-Mycin (Erythromycin) C  
 Flovent (Fluticasone Propionate) C  
 Theo-Dur C  
 Prednisone (Prednisone) C  
 Soma (Carisoprodol) C  
 Proventil Inhaler (Salbutamol) C  
 Tylox C  
 Ativan C

21-Jul-2006 10:28 AM

Page: 35

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/23/02ISR Number: 3953218-6Report Type:Expedited (15-DaCompany Report #PHFR2002GB02202 Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abnormal Behaviour	Foreign	Tegretal					
Other	Acute Psychosis	Health	(Carbamazepine)	PS			200 MG, BID	
	Asphyxia	Professional	Cannabis (Cannabis)	SS				
	Blood Cannabinoids Increased	Other						

Date:07/25/02ISR Number: 3953974-7Report Type:Expedited (15-DaCompany Report #A0373830A Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Homicide	Literature	Paxil	PS		ORAL		

Injury Consumer Cocaine (Formulation Unknown) (Cocaine) SS  
 Diamorphine Hydrochloride (Diamorphine Hydrochloride) SS  
 Cannabis (Cannabis) SS

Date:08/01/02ISR Number: 3958130-4Report Type:Expedited (15-DaCompany Report #A0373107A Age:16 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Acute Psychosis	Foreign	Paxil (Formulation					
Other	Agitation	Literature	Unknown) (Paroxetine					
	Crying	Consumer	Hydrchloride)	PS	ORAL	ORAL	6	MON
	Mental Disorder		Cannabis					
	Nightmare		(Formulation					
	Physical Assault		Unknown) (Cannabis)	SS				
	Psychiatric Symptom		Ethanol (Formulation					
	Schizophrenia		Unknown) (Alcohol)	SS				
	Suicide Attempt							
	Theft							
	Thinking Abnormal							

Date:08/06/02ISR Number: 3959200-7Report Type:Expedited (15-DaCompany Report #2013363 Age:34 YR Gender:Male I/FU:F

Outcome	PT
Death	Accidental Overdose
Hospitalization -	Arthralgia
Initial or Prolonged	Bone Pain
Other	Bronchitis
	Cardiomegaly
	Chest Pain
	Chronic Obstructive Pulmonary Disease
	Coma
	Cough
	Delirium
	Diarrhoea
	Disorientation
	Drug Abuser
	Drug Dependence
	Drug Screen Positive

21-Jul-2006 10:28 AM

Page: 36

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Drug Toxicity	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Drug Withdrawal Syndrome	Health	Oxycontin Tablets 20					
Dyspepsia							
Dyspnoea							

Erectile Dysfunction	Professional	Mg (Oxycodone			
Fall	Other	Hydrochloride) Cr			
Hypertonia		Tablet PS	ORAL	20 MG, ORAL	
Hypoaesthesia		Oxycontin Tablets 40			
Joint Stiffness		Mg (Oxycodone			
Muscular Weakness		Hydrochloride) Cr			
Mydriasis		Tablet SS	ORAL	40 MG, ORAL	
Nocturia		Hydrocodone / Apap			
Pain		(Paracetamol,			
Pain In Extremity		Hydrocodone			
Paraesthesia		Bitartrate) Unknown SS	ORAL	10 MG, SEE	
Pollakiuria			TEXT, ORAL		
Pyrexia		Amitriptyline			
Sluggishness		(Amitriptyline) SS		100 MG, NOCTE 1229 DAY	
Somnolence		Acetaminophen			
Stridor		(Paracetamol) SS		1229 DAY	
Urinary Incontinence		Cannabinoids () SS		1229 DAY	
Vomiting		Tylox (Oxycodone			
Wheezing		Terephthalate) C			
		Ativan (Lorazepam) C			
		Xanax (Alprazolam) C			
		Vioxx (Rofecoxib) C			
		Pamelor			
		(Nortriptyline			
		Hydrochloride) C			
		Ultram C			
		Skelaxin			
		(Metaxalone) C			
		Buspar (Buspirone			
		Hydrochloride) C			
		Tenormin (Atenolol) C			
		Narcan C			
		Ambien (Zolpidem			
		Tartrate) C			
		Haldol (Haloperidol) C			
		Cogentin			
		(Benzatropine			
		Mesilate) C			
		Narcan C			
		Diazepam (Diazepam) C			
		Baclofen (Baclofen) C			
		Lorcet C			
		Toradol (Ketorolac			
		Tromethamine) C			
		Phenergan			
		(Promethazine			
		Hydrochloride) C			
		E-Mycin			
		(Erythromycin) C			
		Flovent (Fluticasone			
		Propionate) C			
		Theo-Dur C			
		Prednisone			
		(Prednisone) C			
		Soma (Carisoprodol) C			
		Proventil Inhaler			
		(Salbutamol) C			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:08/14/02ISR Number: 3963773-8Report Type:Expedited (15-DaCompany Report #2013363

Age:34 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abnormal Behaviour	Health	Oxycontin Tablets 20					
Hospitalization - Initial or Prolonged	Accidental Overdose Aggression	Professional Other	Mg (Oxycodone Hydrochloride) Cr					
Other	Arthralgia		Tablet PS			ORAL	20 MG, ORAL	
	Bone Pain		Oxycontin Tablets 40					
	Bronchitis		Mg (Oxycodone Hydrochloride) Cr					
	Cardiomegaly		Tablet SS			ORAL	40 MG, ORAL	
	Chest Pain		Hydrocodone/Apap (Paracetamol, Hydrocodone Bitartrate)					
	Chronic Obstructive Pulmonary Disease		Hydrocodone Bitartrate)	SS		ORAL	10 MG, SEE TEXT, ORAL	
	Coma		Amitriptyline (Amitriptyline)	SS			100 MG, NOCTE	1229 DAY
	Cough		Acetaminophen (Paracetamol)	SS				1229 DAY
	Delirium		Cannabinoids()	SS				1229 DAY
	Diarrhoea		Tylox (Oxycodone Terephthalate)	C				
	Disorientation		Ativan (Lorazepam)	C				
	Drug Abuser		Xanax (Alprazolam)	C				
	Drug Dependence		Vioxx (Rofecoxib)	C				
	Drug Effect Decreased		Pamelor (Nortriptyline Hydrochloride)	C				
	Drug Toxicity		Ultram	C				
	Drug Withdrawal Syndrome		Skelaxin (Metaxalone)	C				
	Dyspepsia		Buspar (Buspirone Hydrochloride)	C				
	Dyspnoea		Tenormin (Atenolol)	C				
	Erectile Dysfunction		Narcan	C				
	Fall		Ambien (Zolpidem Tartrate)	C				
	Hypertonia		Haldol (Haloperidol)	C				
	Hypoaesthesia		Cogentin (Benzatropine Mesilate)	C				
	Mydriasis		Narcan	C				
	Nocturia		Diazepam (Diazepam)	C				
	Pain In Extremity		Baclofen (Baclofen)	C				
	Paraesthesia		Lorcet	C				
	Pollakiuria		Toradol (Ketorolac Tromethamine)	C				
	Pupillary Disorder		Phenergan (Promethazine Hydrochloride)	C				
	Pyrexia							
	Somnolence							
	Speech Disorder							
	Stridor							
	Suicidal Ideation							
	Urinary Incontinence							
	Urine Analysis Abnormal							
	Vomiting							
	Wheezing							

E-Mycin  
 (Erythromycin) C  
 Flovent (Fluticasone  
 Propionate) C  
 Theo-Dur C  
 Prednisone  
 (Prednisone) C  
 Soma (Carisoprodol) C  
 Proventil Inhaler  
 (Salbutamol) C

21-Jul-2006 10:28 AM

Page: 38

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Percocet Tablet C  
 Penicillin V-K  
 (Phenoxymethylpenici  
 llin Potassium) C

Date:08/27/02ISR Number: 3969169-7Report Type:Expedited (15-DaCompany Report #USA-2002-0001270 Age:16 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiomegaly	Consumer	Oxycontin					
	Drug Dependence	Other	Tablets(Oxycodone					
	Drug Screen Positive		Hydrochloride) Cr					
	Drug Toxicity		Tablet PS					
	Hepatic Congestion		Cannabis(Cannabis)	SS				
	Pulmonary Congestion		Benzodiazepine					
	Pulmonary Oedema		Derivatives()	SS				
	Ventricular Hypertrophy		Opiates()	SS				
			Methadone(Methadone)	SS				
			Alprazolam(Alprazola					
			m)	SS				

Date:08/30/02ISR Number: 3969736-0Report Type:Expedited (15-DaCompany Report #2002004201 Age:16 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Abuser Overdose	Foreign Health	Zeldox (Capsules) (Ziprasidone)	PS		ORAL ORAL	40 MG (BID),	
	Suicide Attempt	Professional	Carbamazepine					
	Toxicologic Test Abnormal		(Carbamazepine)	SS				
			Cannabis (Cannabis)	SS				
			Tricyclic					
			Antidepressants					
			(Tricyclic					
			Antidepressants)	SS				

Outcome PT  
 Hospitalization - Anhedonia  
 Initial or Prolonged Anxiety  
 Other Arthralgia  
 Bronchopneumonia  
 Cytomegalovirus Hepatitis  
 Dehydration  
 Depression  
 Drug Dependence  
 Drug Ineffective  
 Drug Tolerance  
 Drug Withdrawal Syndrome  
 Gastroenteritis  
 Gastrooesophageal Reflux  
 Disease  
 Hiatus Hernia  
 Infection  
 Insomnia  
 Nasal Septum Deviation

21-Jul-2006 10:28 AM

Page: 39

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Orthostatic Hypotension	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Pruritus	Health Professional	Oxycontin Tablets 80 Mg (Oxycodone Hydrochloride) Cr Tablet	PS		ORAL	80 MG, BID, ORAL	
Rhinorrhoea		Oxycontin Tablets 20 Mg(Oxycodone Hydrochloride) Cr Tablet	SS		ORAL	40 MG, BID, ORAL	
Sepsis		Oxyir Capsules 5 Mg (Oxycodone Hydrochloride) Ir Capsule	SS		ORAL	5 MG, DAILY, ORAL	
Sinusitis		Cannabis(Cannabis) Methadone(Methadone) Lortab(Paracetamol, Hydrocodone Bitartrate) Benzodiazepine Derivatives()	SS		ORAL	ORAL	
Somnolence		Prilosec (Omeprazole)	C				
Stress		Prograf (Tacrolimus)	C				
Toxicologic Test Abnormal		Asacol (Mesalazine)	C				

Ambien (Zolpidem  
 Tartrate) C  
 Celexa (Citalopram  
 Hydrobromide) C  
 Prozac (Fluoxetine  
 Hydrochloride) C  
 Ferrous Sulfate  
 (Ferrous Sulfate) C  
 Remeron  
 (Mirtazapine) C  
 Lasix (Furosemide) C  
 Lomotil (Atropine  
 Sulfate,  
 Diphenoxylate  
 Hydrochloride) C  
 Prednisone  
 (Prednisone) C  
 Demerol (Pethidine  
 Hydrochloride) C  
 Buspar (Buspirone  
 Hydrochloride) C  
 Neurontin  
 (Gabapentin) C  
 Clonidine  
 (Clonidine) C  
 Zofran (Ondansetron  
 Hydrochloride) C  
 Nonox C  
 Famvir (Famciclovir) C  
 Benadryl  
 (Diphenhydramine  
 Hydrochloride) C

21-Jul-2006 10:28 AM

Page: 40

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Cefalexin  
 (Cefalexin) C  
 Silvadene  
 (Sulfadiazine  
 Silver) C  
 Ceclor (Cefaclor) C

Date:09/17/02ISR Number: 3980020-1Report Type:Expedited (15-DaCompany Report #USA-2002-0002030

Age:32 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Dependence	Consumer	Oxycontin Tablets					
Other	Drug Withdrawal Syndrome	Other	(Oxycodone Hydrochloride) Cr					
	Overdose		Tablet	PS				
	Toxicologic Test Abnormal		Hydrocodone Bitartrate (Similar					



To Ind 59, 175)  
 (Hydrocodone  
 Bitartrate) SS  
 Methadone  
 (Methadone) SS  
 Marijuana (Cannabis) SS

Date:09/25/02ISR Number: 3981647-3Report Type:Expedited (15-DaCompany Report #PHFR2002GB02202 Age:30 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abnormal Behaviour	Foreign	Tegretal					
Other	Acute Psychosis	Health	(Carbamazepine)	PS			200 MG, BID	
	Asphyxia	Professional	Cannabis (Cannabis)	SS				
	Blood Cannabinoids Increased	Other						

Date:11/07/02ISR Number: 4009072-XReport Type:Expedited (15-DaCompany Report #USA-2002-0002030 Age:32 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Coma	Consumer	Oxycontin Tablets 40					
Other	Depression	Other	Mg (Oxycodone					
	Drug Dependence		Hydrochloride) Cr					
	Drug Withdrawal Syndrome		Tablet	PS		MG		
	Faecal Incontinence		Hydrocodone					
	Overdose		Bitartrate (Similar					
	Pain		To Ind 59, 175)					
	Toxicologic Test Abnormal		(Hydrocodone					
	Urinary Incontinence		Bitartrate)	SS		MG		
			Methadone					
			(Methadone)	SS				
			Marijuana (Cannabis)	SS				
			Alprazolam	C				

21-Jul-2006 10:28 AM

Page: 41

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/20/02ISR Number: 4015719-4Report Type:Expedited (15-DaCompany Report #K200201863 Age:23 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Abuser	Literature	Ketalar					
	Intentional Overdose	Health	(Ketamine) Injection	PS		ORAL	ORAL	
		Professional	Methylenedioxyamphet					
			amine					

(Methylenedioxyamph  
tamine) SS ORAL ORAL  
Marijuana (Cannabis) SS ORAL ORAL

Date:11/21/02ISR Number: 4016861-4Report Type:Expedited (15-DaCompany Report #USA-2002-0003051 Age:26 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aggression	Consumer	Oxycontin (Oxycodon					
Other	Agitation	Other	Hydrochloride) Cr	PS		INTRAVENOUS		
	Cardiac Failure		Cocaine (Cocaine)	SS		INTRAVENOUS		
	Delirium		Amitriptyline					
	Loss Of Consciousness		(Amitriptyline)					
	Overdose		Unknown	SS		UNKNOWN	1 DAY	
	Polysubstance Abuse		Marijuana (Cannabis)					
		Unknown	SS		UNKNOWN		1 DAY	

Date:11/26/02ISR Number: 4017864-6Report Type:Expedited (15-DaCompany Report #PHBS2002AU11185 Age:20 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Depression	Foreign	Clozaril (Clozapine)					
Initial or Prolonged	Drug Abuser	Study	Tablet	PS		ORAL	400 MG/DAY,	
	Hallucination, Auditory	Health				ORAL; 2600		
	Intentional Overdose	Professional				MG,		
	Mental Disorder	Other				ONCE/SINGLE,		
	Suicide Attempt					ORAL		
			Cannabis (Cannabis)	SS				
			Valproate Sodium	C				

Date:12/06/02ISR Number: 4022398-9Report Type:Expedited (15-DaCompany Report #USA-2002-0002748 Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
	Arteriosclerosis	Professional	Hydrochloride					
	Bronchopneumonia	Other	(Similar To Nda					
	Cardiac Failure		20-553) (Oxycodone					
	Congestive		Hydrochloride)	PS				
	Cardio-Respiratory Arrest		Morphine Sulfate					
	Coma		(Similar To Andas					
	Contusion		74-769 And 74-862)					
	Drug Toxicity		(Morphine Sulfate					
	Laceration		Abg)	SS				
			Alprazolam					
			(Alprazolam)	SS				
			Cocaine (Cocaine)	SS				
			Fluoxetine					
			(Fluoxetine)	SS				
			Cannabis (Cannabis)	SS				

Freedom Of Information (FOI) Report

Date:12/12/02ISR Number: 4025593-8Report Type:Expedited (15-DaCompany Report #02P-163-0205261-00

Age:29 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Hydrocodone/Acetamin					
	Health Professional	Health Professional	opphen (Vicodin) (Hydrocodone/Acetaminophen) PS			ORAL		PER ORAL
			Hydromorphone (Dilaudid) (Hydromorphone) (Hydromorphone) SS			ORAL		PER ORAL
			Cannabis SS			ORAL		PER ORAL

Date:12/18/02ISR Number: 4027953-8Report Type:Expedited (15-DaCompany Report #4660

Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agitation	Health Professional	Cisplatin	PS			20 MG/M2; 5	
	Aphasia						DAYS/5 DAYS	
	Carotid Artery Thrombosis		Etoposide	SS			100 MG/M2; 5	
	Cerebral Artery Occlusion						DAYS/5 DAYS	
	Cerebral Haemorrhage		Bleomycin	SS			20 MG/M2; 3	
	Confusional State						DAYS/3 DAYS	
	Drug Dependence		Cannabis	SS			RESPIRATORY	
	Drug Screen Positive						(INHALATION)	
	Haemoglobin Decreased		Magnesium	C				
	Ischaemic Stroke		Prednisolone	C				
	Monoparesis		Tropisetron	C				
	Paraesthesia		Metoclopramide	C				
	Platelet Disorder		Chlorpromazine	C				
	Tinnitus							
	Tonic Convulsion							

Date:12/27/02ISR Number: 4034984-0Report Type:Expedited (15-DaCompany Report #USA-2002-0001349

Age:17 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anoxic Encephalopathy	Health Professional	Oxycontin Tablets 20					
Hospitalization - Initial or Prolonged	Cerebellar Infarction Cyanosis Ischaemia Respiratory Failure Toxicologic Test Abnormal	Professional Other	Mg (Oxycodone Hydrochloride) Cr					
		Tablet	PS			ORAL	20 MG, Q12H,	
			Cannabis (Cannabis)	SS		ORAL	MG	5 DAY
			Alcohol (Ethanol)	SS		ORAL	L, ORAL	5 DAY
			Benzodiazepine ( )	SS			MG	5 DAY
			Prozac (Fluoxetine Hydrochloride)	C				
			Klonopin (Clonazepam)	C				
			Colace	C				
			Zofran (Ondansetron Hydrochloride)	C				

## FDA - Adverse Event Reporting System (AERS)

## Freedom Of Information (FOI) Report

Date:01/06/03ISR Number: 4039860-5Report Type:Expedited (15-DaCompany Report #327851

Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Health	Accutane					
	Panic Attack	Professional	(Isotretinoin)	PS		ORAL	ORAL	
	Photopsia		Marijuana (Cannabis)	SS				

Date:01/29/03ISR Number: 4050343-9Report Type:Expedited (15-DaCompany Report #USA-2002-0002030

Age:32 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anhedonia	Consumer	Oxycontin Tablets 10					
	Anxiety	Health	Mg (Oxycodone					
	Back Pain	Professional	Hydrochloride)	PS		10 MG		
	Coma	Other	Oxycontin Tablets 40					
	Depression		Mg (Oxycontin					
	Drug Abuser		Hydrochloride) Cr					
	Drug Dependence		Tablet	SS		40 MG, BID		
	Drug Withdrawal Syndrome		Hydrocodone					
	Emotional Disorder		Bitartrate					
	Overdose		(Hydrocodone					
	Pain		Bitartrate)	SS		89 DAY		
	Sexual Dysfunction		Oxyir Capsules 5 Mg					
	Toxicologic Test Abnormal		(Oxycodone					
			Hydrochloride) Ir					
			Capsule	SS		5 MG, Q4H		89 DAY
			Methadone					
			(Methadone) Unknown	SS				89 DAY
			Marijuana (Cannabis)	SS				89 DAY
			Xanax (Alprazolam)	C				
			Celebrex (Celecoxib)	C				
			Celexa (Citalopram					
			Hydrobromide)	C				

Date:01/29/03ISR Number: 4050347-6Report Type:Expedited (15-DaCompany Report #327851

Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Health	Accutane					
	Panic Attack	Professional	(Isotretinoin)	PS		ORAL	ORAL	
	Photopsia		Marijuana (Cannabis)	SS				

Date:02/06/03ISR Number: 4051879-7Report Type:Expedited (15-DaCompany Report #FR-GLAXOSMITHKLINE-B0290963A

Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Health	Deroxat	PS	Glaxosmithkline	ORAL	20MG	Per day
	Dyskinesia	Professional	Cannabis	SS		RESPIRATORY		
	Hemiplegia					(INHALATION)		
	Loss Of Consciousness							

Date:02/13/03ISR Number: 4058099-0Report Type:Expedited (15-DaCompany Report #USA-2003-0004866

Age:24 YR Gender:Male I/FU:I

Outcome  
Hospitalization -  
Initial or Prolonged

21-Jul-2006 10:28 AM

Page: 44

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Disability

Other	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Accidental Overdose	Health	Oxycontin Tablets					
Intervention to	Cerebral Infarction	Professional	(Oxycodone					
Prevent Permanent	Convulsion	Company	Hydrochloride) Cr					
Impairment/Damage	Drug Abuser	Representative	Tablet	PS		INTRAVENOUS		INTRAVENOUS
	Respiratory Depression		Marijuana (Cannabis)	SS		RESPIRATORY		
	Skin Ulcer					(INHALATION)		INHALATION
		Amphetamine						
		(Amfetamine)	SS					

Date:02/27/03ISR Number: 4068349-2Report Type:Expedited (15-DaCompany Report #2013363

Age:34 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abnormal Behaviour	Health	Oxycontin Tablets					
Hospitalization -	Accidental Overdose	Professional	20mg (Oxycodone					
Initial or Prolonged	Aggression	Other	Hydrochloride) Cr					
Other	Arthralgia		Tablet	PS		ORAL	20 MG, UNK;	
	Bronchitis					ORAL		
	Cardiomegaly		Oxycontin Tablets 40					
	Chest Pain		Mg (Oxycodone					
	Chronic Obstructive		Hydrochloride) Cr					
	Pulmonary Disease		Tablet	SS		ORAL	40 MG, UNK;	
	Coccydynia					ORAL		
	Coma		Hydrocodone/Apap					
	Delirium		(Paracetamol,					
	Diarrhoea		Hydrocodone					
	Disorientation		Bitartrate) Unknown	SS		ORAL	10 MG, SEE	
	Drug Abuser						TEXT; ORAL	

Drug Dependence	Amitriptyline		
Drug Screen Positive	(Amitriptyline)	SS	100 MG, NOCTE 1229 DAY
Drug Toxicity	Acetaminophen(Parace		
Drug Withdrawal Syndrome	tamol)	SS	1229 DAY
Dyspepsia	Cannabinoids ()	SS	1229 DAY
Dyspnoea	Xanax (Alprazolam)	C	
Erectile Dysfunction	Vioxx (Rofecoxib)	C	
Fall	Pamelor		
Hypertonia	(Nortriptyline		
Hypoaesthesia	Hydrochloride)	C	
Imprisonment	Ultram	C	
Muscular Weakness	Skelaxin		
Mydriasis	(Metaxalone)	C	
Nocturia	Buspar (Buspirone		
Overdose	Hydrochloride)	C	
Pain In Extremity	Tenormin (Atenolol)	C	
Pollakiuria	Narcan	C	
Pupillary Reflex Impaired	Ambien (Zolpidem		
Sexual Dysfunction	Tartrate)	C	
Somnolence	Haldol (Haloperidol)	C	
Speech Disorder	Cogentin		
Toxicologic Test Abnormal	(Benzatropine		
Urinary Incontinence	Mesilate)	C	
Vomiting	Narcan	C	
Wheezing	Diazepam (Diazepam)	C	
	Baclofen	C	
	Lorcet	C	
	Toradol (Ketorolac		
	Tromethamine)	C	

21-Jul-2006 10:28 AM

Page: 45

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Phenergan  
(Promethazine  
Hydrochloride) C  
E-Mycin  
(Erythromycin) C  
Flovent (Fluticasone  
Propionate) C  
Theo-Dur C  
Prednisone C  
Soma (Carisoprodol) C  
Proventil Inhaler  
(Salbutamol) C  
Percocet C  
Penicillin V-K  
(Phenoxymethylpenici  
llin Potassium) C  
Tylox C  
Ativan C

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Abdominal Pain Aggression Anxiety Arthralgia Decreased Appetite Depression Disturbance In Attention Drug Dependence Drug Withdrawal Syndrome Emotional Disorder Fatigue Haematuria Insomnia Loss Of Consciousness Muscle Spasms Nausea Nephrolithiasis Night Sweats Pain Paranoia Photosensitivity Reaction Polysubstance Abuse Psychotic Disorder Rhinorrhoea Suicidal Ideation Suicide Attempt Thermal Burn Tonsillitis Tremor Vomiting Weight Decreased	Consumer Health Professional Other	Oxycontin Tablets 20 Mg (Oxycodone Hydrochloride) Cr (Amfetamine SS Cocaine (Cocaine) SS Marijuana (Cannabis) SS Tylenol W/Codeine No. 3 (Codeine Phosphate, Paracetamol) Tablet SS Tylox (Oxycodone Terephthalate) Tablet SS Lortab (Paracetamol, Hydrocodone Bitartrate) Tablet SS Vicodin (Paracetamol, Hydrocodone Bitartrate) Tablet SS Xanax (Alprazolam) Tablet SS Prazac (Prazosin Hydrochloride) Tablet C Trazodone (Trazodone) C Keflex (Cefalexin Monohydrate) Tablet C					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest Coma Convulsion Overdose Pulmonary Oedema Toxicologic Test Abnormal Wound	Consumer Health Professional Company Representative Other	Oxycontin Tablets (Oxycodone Hydrochloride) Cr (Mg (Oxycodone Hydrochloride) Cr) PS Marijuana (Cannabis) SS Ethanol (Ethanol) SS Sertraline			ORAL	MG, ORAL	

(Sertraline) Tablet SS

Date:03/14/03ISR Number: 4072240-5Report Type:Expedited (15-DaCompany Report #CA-GLAXOSMITHKLINE-A0373107A

Age:16 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Acute Psychosis	Other	Paxil	PS	Glaxosmithkline	ORAL		6 MON
Other	Aggression		Marijuana	SS				
	Agitation		Alcohol	SS				
	Collapse Of Lung							
	Crying							
	Injury							
	Intentional Self-Injury							
	Nightmare							
	Pericardial Effusion							
	Psychiatric Symptom							
	Suicide Attempt							
	Thinking Abnormal							

Date:04/04/03ISR Number: 4089950-6Report Type:Expedited (15-DaCompany Report #PHRM2002FR01226

Age:21 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Foreign	Trileptal					
	Sudden Death	Health	(Oxcarbazepine)					
		Professional	Tablet	PS		ORAL	600 MG/DAY,	
		Company				ORAL		
		Representative	Urbanyl (Clobazam)					
		Other	Tablet	SS		ORAL	10 MG TID,	
						ORAL		
			Subutex					
			(Buprenorphine					
			Hydrochloride)					
			Tablet	SS		ORAL	4 MG/DAY,	
						ORAL		
			Cannabis (Cannabis)	SS				
			Alcohol (Ethanol)					
			Solution	SS		ORAL	ORAL	
			Lexomil (Bromazepam)					
			Tablet	SS		ORAL	PRN, ORAL	
			Nozinan Tablet	C				

Date:04/08/03ISR Number: 4091544-3Report Type:Expedited (15-DaCompany Report #USA-2003-0005153

Age:48 YR Gender:Male I/FU:I

Outcome	PT
Death	Drug Screen Positive
	Internal Injury

21-Jul-2006 10:28 AM

Page: 47

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report



Polysubstance Abuse  
Road Traffic Accident

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Consumer Health Professional Other	Oxycodone Hydrochloride	PS		MG		
	Amfetamine	SS		MG		
	Methadone (Methadone)	SS		MG		
	Metamfetamine (Metamfetamine)	SS		MG		
	Diazepam (Diazepam)	SS		MG		
	Temazepam (Temazepam)	SS		MG		
	Fluoxetine (Fluoxetine)	SS		MG		
	Marijuana(Cannabis)	SS				
	Atropine Sulfate (Atropine Sulfate)	SS		MG		

Date:04/11/03ISR Number: 4094217-6Report Type:Expedited (15-DaCompany Report #USA-2003-0005330

Age:56 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Consumer Health Professional Other	Oxycontin Tablets (Oxycodone Hydrochloride) Cr Tablet	PS				
	Chronic Obstructive Pulmonary Disease		Roxicodone (Oxycodone Hydrochloride)	SS		RESPIRATORY (INHALATION)		
	Drug Toxicity		Cocaine (Cocaine)	SS				
	Nasopharyngitis		Zoloft (Sertraline Hydrochloride)	C				
	Somnolence		Prinivil (Lisinopril)	C				
	Toxicologic Test Abnormal		Diovane (Valsartan)	C				
			Vioxx (Rofecoxib)	C				
			Valium (Diazepam)	C				
			Albuterol (Salbutamol)	C				
			Furosemide (Furosemide)	C				
			Catapres (Clonidine)	C				

Date:04/11/03ISR Number: 4094544-2Report Type:Expedited (15-DaCompany Report #12219549

Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Cannabinoids Increased	Foreign Literature	Cisplatin	PS		INTRAVENOUS	20 MG/M2,	
	Carotid Artery Thrombosis	Health	Vepesid			CYCLE IV		
	Cerebral Artery Occlusion	Professional Company	Inj(Etoposide)	SS		INTRAVENOUS	100 MG/M2,	
	Haemoglobin Decreased					CYCLE IV		

Ischaemic Stroke Representative Bleomycin Hcl SS INTRAVENOUS 20 MG/M2,  
 Platelet Count Increased Other Cannabis SS CYCLE IV  
 Tinnitus Magnesium

21-Jul-2006 10:28 AM

Page: 48

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

(Magnesium) C  
 Prednisolone  
 (Prednisolone) C  
 Tropisetron  
 (Tropisetron Hcl) C  
 Metoclopramide  
 (Metoclopramide Hcl) C  
 Chlorpromazine  
 (Chlorpromazine) C

Date:04/14/03ISR Number: 4090104-8Report Type:Expedited (15-DaCompany Report #SE-ROCHE-242745 Age:23 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Aggression		Valium	PS	Roche	UNKNOWN		
	Amnesia		Flunitrazepam	SS	Roche	ORAL		
	Antisocial Personality Disorder		Flunitrazepam	SS	Roche	ORAL		
	Disorder		Amphetamine	SS		UNKNOWN		
	Dissociative Disorder		Cannabis	SS		RESPIRATORY		
	Fatigue				(INHALATION)			
	Hallucination, Auditory		Alcohol	SS		ORAL		
	Homicide							
	Narcissistic Personality Disorder							
	Paranoia							
	Positron Emission Tomogram Abnormal							
	Thinking Abnormal							

Date:04/15/03ISR Number: 4095820-XReport Type:Expedited (15-DaCompany Report #PHNU2003DE01438 Age:38 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Delirium	Foreign	Tegretal					
	Drug Screen Positive	Health	Retard(Carbamazepine					
	Hallucination	Professional	) Extended Release					
	Laceration	Other	Tablet	PS		ORAL	SEE IMAGE	
	Overdose		Cannabis	SS				
	Self Mutilation		Aponal (Doxepin Hydrochloride)	C				
			Promethazine					
			Sugar-Coated Tablet	C				

Outcome PT  
 Death Anhedonia  
 Other Anxiety  
 Back Pain  
 Coma  
 Depression  
 Drug Abuser  
 Drug Dependence  
 Drug Screen Positive  
 Drug Withdrawal Syndrome  
 Faecal Incontinence  
 Insomnia  
 Overdose

21-Jul-2006 10:28 AM

Page: 49

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Pain  
 Sexual Dysfunction  
 Urinary Incontinence

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Consumer	Oxycontin Tablets 10					
Health Professional	Mg (Oxycodone Hydrochloride)Cr					
Other	Tablet PS			10 MG		
	Oxycontin Tablets 40					
	Mg (Oxycodone Hydrochloride) Cr					
	Tablet SS			40 MG, BID		
	Hydrocodone Bitartrate (Similar To Ind 59, 175)(Hydrocodone Bitartrate) Unknown	SS				89 DAY
	Oxyir Capsules 5 Mg (Oxycodone Hydrochloride) Ir	SS		5 MG, Q4H		89 DAY
	Methadone (Methadone)	SS				89 DAY
	Marijuana (Cannabis)	SS				89 DAY
	Xanax (Alprazolam)	C				
	Celebrex (Celecoxib)	C				
	Celexa (Citaloprm Hydrobomide)	C				

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Duragesic ( 100 Mcg/ Hr Patch) (Fentanyl)	PS		TRANSDERMAL	100 MCG/H,	

Endocardial Disease		TRANSD
Haemorrhage	Darvon	
Overdose	(Dextropropoxyphene	
Petechiae	Hydrochloride) SS	
Pleural Disorder	Ritalin	
Pulmonary Congestion	(Methylphenidate	
Pulmonary Oedema	Hydrochloride) SS	
Respiratory Arrest	Marijuana (Cannabis) SS	
Toxicologic Test Abnormal		

Date:05/14/03ISR Number: 4109290-6Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0407380A Age:32 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Consumer	Paxil	PS	Glaxosmithkline			
	Memory Impairment		Alcohol	SS				
	Somnolence		Cocaine	SS				
	Speech Disorder		Marijuana	SS				
	Thought Blocking		Ecstasy	SS				
		Nitrous Oxide	SS					

21-Jul-2006 10:28 AM

Page: 50

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/15/03ISR Number: 4112929-2Report Type:Expedited (15-DaCompany Report #PHEH2003US03697 Age:16 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Brain Oedema	Other	Ritalin					
	Endocardial Disease		(Methylphenidate					
	Haemorrhage		Hydrochloride)					
	Intentional Overdose		Tablet PS					
	Medication Tampering		Fentanyl(Fentanyl)	SS		TRANSDERMAL	100 MCG/HR,	
	Petechiae					TRANSDERMAL		
	Pleural Haemorrhage		Dextropropoxyphene(D					
	Pulmonary Congestion		extropropoxyphene)	SS				
	Pulmonary Oedema		Marijuana(Cannabis)	SS				
	Respiratory Arrest							
	Toxicologic Test Abnormal							

Date:06/06/03ISR Number: 4142342-3Report Type:Periodic Company Report #312008 Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Depression	Health	Accutane					
Intervention to	Drug Interaction	Professional	(Isotretinoin) 40 Mg	PS		ORAL	2 PER DAY	
Prevent Permanent	Suicidal Ideation					ORAL		
Impairment/Damage			Marijuana (Cannabis)	SS		ORAL	ORAL	

Date:07/02/03ISR Number: 4181042-0Report Type:Periodic Company Report #NSADSS2002032634 Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bradycardia	Literature	Fentanyl (Patch)					
	Coma	Health	(Fentanyl)	PS		INGESTION - INTENTIONAL		
	Drug Abuser	Professional				ABUSE		
	Pyrexia							
	Respiratory Failure		Alprazolam	SS		INTENTIONAL		
						ABUSE		
			Cocaine	SS		INTENTIONAL		
						ABUSE		
			Marijuana (Cannabis)	SS				

Date:07/07/03ISR Number: 4144385-2Report Type:Expedited (15-DaCompany Report #03P-167-0222893-00 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Maternal Drugs Affecting Foetus	Foreign Health Professional	Erythromycin Base (Erythromycin Base)					
	Neonatal Disorder		Filmtabs (Erythromycin)	PS				
	Premature Baby		Betamethasone	SS				
	Small For Dates Baby							
			Cannabis	SS				
			Total Parenteral Nutrition	C				
			Lipids	C				

21-Jul-2006 10:28 AM

Page: 51

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/08/03ISR Number: 4145106-XReport Type:Expedited (15-DaCompany Report #03P-167-0222280-00 Age:25 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Agitation	Foreign Health Professional	Erythromycin Base (Erythromycin Base)					
	Asthenia		Filmtabs (Erythromycin)	PS		ORAL	2 DOSES GIVEN ONLY, PER	
	Bradycardia					ORAL		
	Circulatory Collapse							
	Complications Of Maternal Exposure To Therapeutic Drugs							
	Difficulty In Walking		Cannabis	SS				
	Drug Abuser		Betamethasone	SS		INTRAMUSCULAR	12 MG, 1 IN 1	
	Hypocalcaemia					D,		

Hypomagnesaemia						INTRAMUSCULAR
Maternal Drugs Affecting			Ferrous Sulfate	C		
Foetus			Suspected Iv Drug			
Muscular Weakness			Use (Drug Not			
Premature Labour			Confirmed)	C		
Premature Rupture Of			Potassium Chloride	C		
Membranes			Sandocal "Novartis"	C		
Renal Tubular Acidosis			Sodium Bicarbonate	C		
			Folic Acid	C		

Date:08/04/03ISR Number: 4163552-5Report Type:Periodic Company Report #0254-02(0) Age:52 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Dehydration	Foreign	Baclofen Tablets					
Hospitalization -	Grand Mal Convulsion	Health	(Unknown Strength)					
Initial or Prolonged		Professional	Usp (Danbury/Watson)	PS		ORAL	60 MG DAILY	
					PO			
			Cannador	SS	ORAL	8 DF DAILY PO		
			Dantrolene	SS	ORAL	150 MG DAILY		
					PO			

Date:08/05/03ISR Number: 4171417-8Report Type:Expedited (15-DaCompany Report #2003-07-1542 Age:26 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Abuser	Foreign	Peg - Interferon					
Initial or Prolonged	Drug Withdrawal Syndrome	Study	(Peginterferon Alfa					
Other	Hyperventilation	Health	- 2b) Injectable					
Required	Mental Disorder	Professional	Powder	PS		SUBCUTANEOUS	100 MCG QWK	
Intervention to	Tetany					SUBCUTANEOUS		
Prevent Permanent			Rebetol (Ribavirin0					
Impairment/Damage			Capsules	SS		ORAL	1000 MG QD	
						ORAL		
			Cannabis	SS				
			Methadone Oral					
			Soultion	SS	ORAL	UNK ORAL		

Date:08/06/03ISR Number: 4162319-1Report Type:Expedited (15-DaCompany Report #PHNU2003DE01438 Age:38 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization -	Delirium
Initial or Prolonged	Hallucination
	Laceration

21-Jul-2006 10:28 AM

Page: 52

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Overdose  
Self Mutilation

Toxicologic Test Abnormal	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Tegretal Retard	PS Novartis Sector:	Pharma	ORAL	100 mg, QD	1440 MIN	
	Tegretal Retard	SS Novartis Sector:	Pharma	ORAL	100 mg, BID	1440 MIN	
	Tegretal Retard	SS Novartis Sector:	Pharma	ORAL	300mg/day	1440 MIN	
	Tegretal Retard	SS Novartis Sector:	Pharma	ORAL	7.4 g, ONCE/SINGLE	1440 MIN	
	Cannabis	SS		UNKNOWN			
	Tegretal Retard	SS Novartis Sector:	Pharma	ORAL	300mg/day		
	Aponal	C		ORAL	350mg/day		
	Promethazine	C		ORAL	350mg/day		

Date:08/07/03ISR Number: 4167210-2Report Type:Expedited (15-DaCompany Report #2003032024 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Delusion	Health	Viagra (Sildenafil)	PS		NASAL	NASAL	
Initial or Prolonged	Disorientation	Professional	Ethanol (Ethanol)	SS				
Other	Emotional Disorder		Cannabis (Cannabis)	SS				
	Hallucination							
	Hyperacusis							
	Insomnia							
	Medication Error							
	Psychotic Disorder							
	Pyrexia							
	Speech Disorder							
	Thinking Abnormal							

Date:08/14/03ISR Number: 4167829-9Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0373830A Age:32 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Homicide		Paxil	PS	Glaxosmithkline	ORAL		
	Injury		Cocaine	SS				
			Marijuana	SS				
			Heroin	C				

Date:08/18/03ISR Number: 4169260-9Report Type:Expedited (15-DaCompany Report #AU-GLAXOSMITHKLINE-B0306190A Age:1 DY Gender:Male I/FU:I

Outcome	PT
Other	Body Temperature
	Increased
	Bradycardia Neonatal
	Diarrhoea
	Dyskinesia
	Feeding Disorder Neonatal
	Feeling Jittery
	Maternal Drugs Affecting
	Foetus
	Neonatal Disorder

Respiratory Rate

21-Jul-2006 10:28 AM

Page: 53

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Increased

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Paroxetine Hydrochloride	PS	Glaxosmithkline		40MG Per day	
	Cannabis	SS		5UNIT per day		
	Cephalexin	SS	Glaxosmithkline		1 WK	

Date:08/18/03ISR Number: 4172032-2Report Type:Expedited (15-DaCompany Report #2003-BP-05767RO Age:35 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Abuser	Literature	Cocaine Hcl Topical Solution, 10% (Cocaine)	PS		RESPIRATORY (INHALATION) RT		
			Marijuana (Cannabis)	SS		RESPIRATORY (INHALATION) RT		

Date:08/21/03ISR Number: 4171289-1Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-10660777 Age:36 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Other	Aggression Chest Pain		Stadol Nasal Spray	PS	Bristol-Myers Squibb Company	NASAL	1 YR	
	Dependence Depression		Stadol Nasal Spray	SS	Bristol-Myers Squibb Company	NASAL	1 YR	
	Drug Abuser		Marijuana	SS				
	Epistaxis		Hashish	SS				
	Joint Stiffness							
	Migraine							
	Mood Swings							
	Muscle Spasms							
	Muscle Tightness							
	Sexually Transmitted Disease							
	Suicide Attempt							

Date:08/27/03ISR Number: 4180644-5Report Type:Expedited (15-DaCompany Report #2003032024 Age:23 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Delusion Disorientation Hallucination	Health Professional	Viagra (Sildenafil) Ethanol (Ethanol) Cannabis (Cannabis)	PS SS		NASAL	NASAL	
	Hyperacusis							



Insomnia  
 Mania  
 Medication Error  
 Mental Impairment  
 Paranoia  
 Psychotic Disorder  
 Pyrexia  
 Speech Disorder  
 Thinking Abnormal

21-Jul-2006 10:28 AM

Page: 54

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/03/03ISR Number: 4178063-0Report Type:Expedited (15-DaCompany Report #WAES 0308USA02600 Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agitation	Health	Stromectol	PS	ORAL		1 DAY	
Hospitalization -	Coma	Professional	Alcohol	SS	Merck & Co., Inc	ORAL		1 DAY
Initial or Prolonged	Headache		Alcohol	SS	ORAL		1 DAY	
	Palpitations		Cannabis	SS	ORAL		1 DAY	
	Vertigo		Cannabis	SS	ORAL		1 DAY	

Date:09/09/03ISR Number: 4188541-6Report Type:Expedited (15-DaCompany Report #USA-2003-0008663 Age:40 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Drug Abuser	Health	Oxycontin	PS		INTRAVENOUS	80 MG,	
Hospitalization -	Extradural Haematoma	Professional					INTRAVENOUS	
Initial or Prolonged	Fall	Company	Cocaine (Cocaine)	SS				
Disability	Head Injury	Representative	Heroin (Diamorphine)	SS				
Other	Intentional Drug Misuse		Marijuana (Cannabis)	SS				
Required	Loss Of Consciousness		Amfetamine					
Intervention to	Overdose		(Amfetamine)	SS				
Prevent Permanent	Self-Medication							
Impairment/Damage								

Date:09/10/03ISR Number: 4183062-9Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLIN-B0308644A Age:43 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Optic Neuropathy		Combivir	PS	Glaxosmithkline			
			Nevirapine	SS				
			Ibuprofen	SS	Glaxosmithkline			
			Marijuana	SS				

Date:09/15/03ISR Number: 4185926-9Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLIN-B0308948A Age:33 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Aggression	Consumer	Seroxat	PS	Glaxosmithkline	ORAL		
	Homicide		Alcohol	SS	ORAL			
	Treatment Noncompliance		Cannabis	SS				

Date:09/17/03ISR Number: 4192864-4Report Type:Expedited (15-DaCompany Report #USA-2003-0006203

Age:36 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Abdominal Pain Upper Alcoholism
Other	Anxiety
	Arthralgia
	Depression
	Drug Abuser
	Drug Dependence
	Drug Tolerance
	Drug Withdrawal Syndrome
	Emotional Distress
	Gastritis
	Headache
	Insomnia

21-Jul-2006 10:28 AM

Page: 55

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Nausea								
Pain								
Polysubstance Dependence		Consumer	Oxycontin Tablets					
Refusal Of Treatment By Patient	Health	(Oxycodone						
Sickle Cell Anaemia With Crisis	Other	Professional Tablet	Hydrochloride) Cr			INTRAVENOUS		INTRAVENOUS
Vomiting		Demerol (Pethidine Hydrochloride)	SS			INTRAVENOUS		INTRAVENOUS
		Dilaudid (Hydromorphone Hydrochloride)	SS			INTRAVENOUS		INTRAVENOUS
		Cocaine (Cocaine)	SS					
		Alcohol (Ethanol)	SS			ORAL	12, DAILY,	
						ORAL		
		Marijuana (Cannabis)	SS					
		Percodan (Phenacetin, Homatropine Terephthalate, Oxycodone)	SS					
		Humulin (Insulin Isophane, Human Biosynthetic, Insulin Human)	C					
		Folic Acid (Folic Acid)	C					

Zoloft (Sertraline Hydrochloride) C  
 Hydrochlorothiazide (Hydrochlorothiazide) C  
 Paxil (Paroxetine Hydrochloride) C  
 Restoril (Temazepam) C  
 Vitamin E (Tocopherol) C  
 Prevacid (Lansoprazole) C  
 Celebrex (Celecoxib) C  
 Zantac (Ranitidine Hydrochloride) C

Date:09/22/03ISR Number: 4193848-2Report Type:Expedited (15-DaCompany Report #USA-2003-0009562 Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anoxic Encephalopathy	Health	Ms Contin Tablets					
Hospitalization - Initial or Prolonged	Cyanosis	Professional	(Morphine Sulfate) Cr Tablet	PS			30 MG, BID	
Other	Lethargy		Benzodiazepines	SS				
Required	Medication Error		Marijuana (Cannabis)	SS				
Intervention to Prevent Permanent Impairment/Damage			Tricyclic (Antidepressants)	SS				
			Lortab	C				

21-Jul-2006 10:28 AM

Page: 56

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/22/03ISR Number: 4195026-XReport Type:Expedited (15-DaCompany Report #200304336 Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Optic Neuropathy	Foreign	Unspecified					
	Other		Ibuprofen Product (Ibuprofen)	PS				
			Combivir (Lamivudine/Zidovudine)	SS				
			Nevirapine	SS				
			Cannabis Sativa	SS				

Date:09/25/03ISR Number: 4200374-0Report Type:Expedited (15-DaCompany Report #HQWYE677712SEP03

Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Optic Neuropathy	Health Professional Other	Advil (Ibuprofen, Tablet, 200 Mg) Cannabis (Cannabis, ) Combivir (Lamivudine/Zidovudine, ) Nevirapine (Nevirapine, )	PS		300 MG		

Date:09/26/03ISR Number: 4199360-9Report Type:Expedited (15-DaCompany Report #2003-UK-00522UK Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Optic Neuropathy	Health Professional Other	Nevirapine (00015/0215/A) (Nevirapine) (Nr) Combivir (Nr) (Nevirapine) Ibuprofen (Ibuprofen) (Nr) Cannabis (Cannabis) (Nr)	PS		300 MG		

Date:09/26/03ISR Number: 4200050-4Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20030904399 Age:15 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest Drug Abuser	Literature Health Professional Distributor	Ultram (Tramadol Hydrochloride) Tablets Heroin (Diamorphine) Marijuana (Cannabis)	PS SS SS		ORAL ORAL RESPIRATORY (INHALATION) INHALATION		

Date:09/29/03ISR Number: 4201736-8Report Type:Expedited (15-DaCompany Report #GBWYE304518SEP03 Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source
Other	Optic Neuropathy	Health Professional

21-Jul-2006 10:28 AM

Page: 57

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Other

Product	Role	Manufacturer	Route	Dose	Duration
Advil (Ibuprofen, Tablet, 0)	PS				

Cannabis (Cannabis,  
0 ) SS  
Combivir  
(Lamivudine/Zidovudi  
ne, , 0) SS  
Nevirapine  
(Nevirapine, , 0) SS

Date:09/30/03ISR Number: 4203011-4Report Type:Expedited (15-DaCompany Report #USA-2003-0005884

Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Accidental Overdose Agitation Alcoholism	Consumer Health Professional	Oxycontin Tablets(Oxycodone Hydrochloride)Cr					
	Anxiety	Other	Tablet	PS		ORAL	80 MG, SEE TEXT, ORAL	
	Arthralgia							
	Bipolar I Disorder		Xanax (Alprazolam)	SS				
	Blood Glucose Increased		Cocaine (Cocaine)	SS				
	Blood Pressure Increased		Marijuana (Cannabis)	SS				
	Blood Prolactin Increased		Klonopin					
	Bronchitis		(Clonazepam)	C				
	Depressed Level Of Consciousness		Neurontin (Gabapentin)	C				
	Depression		Flexeril					
	Drug Abuser		(Cyclobenzaprine Hydrochloride)	C				
	Drug Dependence		Doxepin (Doxepin)	C				
	Drug Withdrawal Syndrome		Remeron					
	Feeling Of Despair		(Mirtazapine)	C				
	Galactorrhoea		Trazodone(Trazodone)	C				
	Headache		Ambien (Zolpidem Tartrate)	C				
	Mydriasis		Zanaflex (Tizanidine Hydrochloride)	C				
	Pain		Clonidine (Clonidine)	C				
	Pain In Extremity		Atarax(Hydroxyzine Hydrochloride)	C				
	Polysubstance Abuse		Ativan (Lorazepam)	C				
	Respiratory Rate Decreased		Vicodin	C				
	Sedation		Inderal (Propranolol Hydrochloride)	C				
	Treatment Noncompliance		Ultram	C				
			Naprosyn (Naproxen)	C				
			Valium (Diazepam)	C				
			Risperdal (Risperidone)	C				
			Depakote (Valproate Semisodium )	C				
			Thiamine (Thiamine)	C				
			Mellaril (Thioridazine Hydrochloride)	C				
			Imitrex (Sumatriptan					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Succinate) C  
 Lithium (Lithium) C  
 Seroquel  
 (Quetiapine) C  
 Cigebtub  
 (Benzatropine  
 Mesilate) C  
 Tylenol W/Codeine  
 No. 3 C  
 Albuterol  
 (Salbutamol) C

Date:10/03/03ISR Number: 4204958-5Report Type:Expedited (15-DaCompany Report #USA-2003-0008728 Age:37 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycontin Tablets					
Other	Cardiomegaly	Professional	(Oxycodone					
	Coma	Company	Hydrochloride) Cr					
	Drug Abuser	Representative	Tablet	PS		INTRAVENOUS	INTRAVENOUS	
	Drug Screen Positive	Other	Cocaine (Cocaine)	SS				
	Multiple Drug Overdose		Marijuana (Cannabis)					
	Nervous System Disorder		Unknown	SS		UD		
	Pulmonary Oedema		Chlorpheniramine					
		(Chlorpheniramine)	SS					

Date:10/07/03ISR Number: 4207347-2Report Type:Expedited (15-DaCompany Report #2003178452US Age:23 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Literature	Alprazolam					
	Drug Abuser	Health	(Alprazolam) Tablet	PS				
	Polysubstance Abuse	Professional	Oxycodone					
	Respiratory Arrest		(Oxycodone)	SS				
			Marijuana (Cannabis)	SS				

Date:10/09/03ISR Number: 4209222-6Report Type:Expedited (15-DaCompany Report #KII-2003-0003105 Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alanine Aminotransferase	Health	Oxycodone					
	Aspartate	Professional	Hydrochloride					
	Aminotransferase		(Similar To Nda					
	Blood Alkaline		20-553)(Oxycodone					
	Phosphatase		Hydrochloride)	PS		ORAL	ORAL	
	Blood Potassium		Cocaine(Cocaine)	SS				
	Drug Screen Positive		Marijuana(Cannabis)	SS				
	Prothrombin Time		Benzodiazepine					
	Respiratory Rate		Derivatives	SS				
	Increased		Acetaminophen(Parace					

Tachycardia tamol) SS

Date:10/10/03ISR Number: 4205880-0Report Type:Expedited (15-DaCompany Report #GB-GLAXOSMITHKLINE-B0308644A Age:43 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Optic Neuropathy Visual Disturbance		Combivir	PS	Glaxosmithkline	ORAL per day	450MG	Twice

21-Jul-2006 10:28 AM

Page: 59

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Nevirapine	SS		ORAL	200MG	Twice	
			per day			
Ibuprofen	SS	Glaxosmithkline	ORAL			
Marijuana	SS		RESPIRATORY			
			(INHALATION)			
Vioxx	C		ORAL			
Salbutamol	C	Glaxosmithkline	ORAL			
Unspecified Drug	C		ORAL			
Seretide	C	Glaxosmithkline				

Date:10/15/03ISR Number: 4210194-9Report Type:Expedited (15-DaCompany Report #GBWYE304518SEP03 Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Optic Neuropathy	Foreign Health Professional	Advil (Ibuprofen, Tablet, 0) Cannabis (Cannabis, , 0) Comvivor (Lamivudine/Zidovudi ne, , 0) Nevirapine (Nevirapine, , 0)	PS SS SS			300MG	

Date:10/15/03ISR Number: 4210551-0Report Type:Expedited (15-DaCompany Report #HQWYE677712SEP03 Age:43 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Optic Neuropathy	Health Professional Other	Advil (Ibuprofen, Tablet, 200 Mg) Cannabis (Cannabis, ) Comvivor (Lamivudine/Zidovudi ne, ) Nevirapine (Nevirapine, )	PS SS SS			300 MG	

Outcome PT  
 Death Acidosis  
 Agitation  
 Alanine Aminotransferase  
 Increased  
 Aspartate  
 Aminotransferase  
 Increased  
 Blood Bicarbonate  
 Decreased  
 Blood Pressure Decreased  
 Body Temperature  
 Decreased  
 Bundle Branch Block Right  
 Cardiac Arrest  
 Coma  
 Drug Abuser

21-Jul-2006 10:28 AM

Page: 60

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Drug Screen Positive

Drug Toxicity

Grimacing

Miosis

Pco2 Increased

Po2 Increased

Respiratory Arrest

Report Source

Literature

Health

Professional

Distributor

Product

Ultram (Tramadol

Hydrochloride)

Tablets

Temazepam

(Temazepam) SS

Heroin (Diamorphine) SS

Ethanol (Ethanol) SS

Marijuana (Cannabis) SS

Role

PS

Manufacturer

ORAL

PARENTERAL

Route

ORAL

ORAL

Dose

ORAL

PARENTERAL

Duration

Outcome PT  
 Hospitalization - Accidental Overdose  
 Initial or Prolonged Agitation  
 Other Alcohol Withdrawal  
 Syndrome  
 Alcoholism  
 Aneurysm  
 Anxiety  
 Arthralgia  
 Asthenia  
 Asthma  
 Bipolar Disorder  
 Bipolar I Disorder  
 Blood Glucose Decreased



Blood Glucose Increased  
 Bronchitis  
 Chest Pain  
 Chills  
 Depressed Level Of  
 Consciousness  
 Depression  
 Dizziness  
 Drug Abuser  
 Drug Dependence  
 Drug Withdrawal Syndrome  
 Dysarthria  
 Dyspnoea  
 Dysuria  
 Eye Disorder  
 Feeling Jittery  
 Feeling Of Despair  
 Formication  
 Galactorrhoea  
 Gastroenteritis Viral  
 Hallucination, Auditory  
 Headache  
 Heart Rate Increased  
 Hyperhidrosis  
 Hypertension  
 Lethargy  
 Ligament Injury  
 Logorrhoea  
 Lymphadenopathy  
 Migraine  
 Multiple Drug Overdose

21-Jul-2006 10:28 AM

Page: 61

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Adverse Event	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Mydriasis							
Nausea							
Night Sweats	Consumer	Oxycontin Tablets					
Pain	Health	(Oxycodone					
Pain In Extremity	Professional	Hydrochloride) Cr					
Polysubstance Abuse	Other	Tablet	PS		ORAL	80 MG, SEE	
Pulmonary Congestion					TEXT, ORAL		
Pyrexia							
Respiratory Rate		Xanax (Alprazolam)	SS				
Decreased		Cocaine(Cocaine)	SS				
Sedation		Marijuana (Cannabis)	SS				
Self-Medication		Neurontin					
Sinusitis		(Gabapentin)	C				
Thirst		Flexeril					
Tongue Disorder		(Cyclobenzaprine					
Tremor		Hydrochloride)	C				
Ulcer		Doxepin (Doxepin)	C				
Vision Blurred		Remeron					
		(Mirtazapine)	C				

Trazodone  
(Trazodone) C  
Ambien (Zolpidem  
Tartrate) C  
Zanaflex (Tizanidine  
Hydrochloride) C  
Clonidine  
(Clonidine) C  
Klonopin  
(Clonazepam) C  
Atarax (Hydroxyzine  
Hydrochloride) C  
Ativan (Lorazepam) C  
Vicodin C  
Inderal (Propranolol  
Hydrochloride) C  
Ultram C  
Naprosyn (Naproxen) C  
Valium (Diazepam) C  
Risperdal  
(Risperidone) C  
Depakote (Valproate  
Semisodium) C  
Thiamine (Thiamine) C  
Mellaril  
(Thioridazine  
Hydrochloride) C  
Imitrex (Sumatriptan  
Succinate) C  
Lithium (Lithium) C  
Seroquel  
(Quetiapine) C  
Cogentin  
(Benzatropine  
Mesilate) C  
Tylenol W/Codeine  
No. 3 C  
Albuterol  
(Salbutamol) C  
Haldol (Haloperidol) C  
Imitrex Glaxo  
(Sumatriptan) C

21-Jul-2006 10:28 AM

Page: 62

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Librium Hoffman  
(Chlordiazepoxide  
Hydrochloride) C  
Atenolol (Atenolol) C

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Dependence Weight Decreased	Consumer Health Professional	Oxycontin Tablets (Oxycodone Hydrochloride) Cr Tablet PS Marijuana(Cannabis) SS Cocaine(Cocaine) SS Vicodin(Paracetamol, Hydrocodone Bitartrate) SS Percocet(Paracetamol , Oxycodone Hydrochloride) SS					

Date:10/24/03ISR Number: 4220117-4Report Type:Expedited (15-DaCompany Report #KII-2003-0004027 Age:31 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Apnoea Coma Cyanosis Drug Ineffective Metabolic Acidosis Multiple Drug Overdose Suicide Attempt	Health Professional	Oxycontin Tablets (Oxycodone Hydrochloride) Cr Tablets PS Xanax (Alprazolam) SS Soma (Carisoprodol) SS Cannabis (Cannabis) SS					

Date:10/27/03ISR Number: 4218079-9Report Type:Expedited (15-DaCompany Report #PHEH2003US09662 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Drug Screen Positive		Lotrel Xanax SS Cannabis SS Alcohol SS	PS	Novartis Sector: Pharma			

Date:10/27/03ISR Number: 4220799-7Report Type:Expedited (15-DaCompany Report #USA-2003-0007382 Age:33 YR Gender:Male I/FU:F

Outcome	PT
Death	Aortic Arteriosclerosis Aspiration Bacterial Infection Bronchopneumonia Cardiomegaly Coronary Artery Stenosis Drug Screen Positive Hepatitis B Hepatitis C

Freedom Of Information (FOI) Report

Lymphadenopathy							
Pulmonary Congestion							
Pulmonary Oedema	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Spinal Osteoarthritis	Health	Oxycodone					
	Professional	Hydrochloride					
	Other	(Oxycodone					
		Hydrochloride)	PS				
		Methadone					
		(Methadone)	SS				
		Cannabis (Cannabis)	SS				
		Nicotine (Nicotine)	SS				

Date:10/28/03ISR Number: 4222760-5Report Type:Expedited (15-DaCompany Report #USA-2003-0005884

Age:34 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization -	Abdominal Pain
Initial or Prolonged	Accidental Overdose
Other	Agitation
	Alcohol Withdrawal
	Syndrom
	Aneurysm
	Anxiety
	Apnoea
	Arthralgia
	Asthenia
	Asthma
	Bipolar I Disorder
	Blood Prolactin Increased
	Bronchitis
	Chills
	Cholelithiasis
	Confusional State
	Costochondritis
	Depressed Level Of
	Consciousness
	Depression
	Diabetes Mellitus
	Inadequate Control
	Diarrhoea
	Dizziness
	Drug Abuser
	Drug Dependence
	Drug Ineffective
	Drug Screen Positive
	Drug Withdrawal Syndrome
	Dysarthria
	Dysuria
	Eye Disorder
	Feeling Abnormal
	Formication
	Gait Disturbance
	Galactorrhoea
	Gastroenteritis Viral

Hallucination, Auditory  
 Headache  
 Heart Rate Increased  
 Hyperhidrosis  
 Hypertension  
 Lethargy

21-Jul-2006 10:28 AM

Page: 64

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Adverse Event	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Ligament Injury							
Logorrhoea							
Lymphadenopathy	Consumer	Oxycontin Tablets	PS		ORAL	80 MG, SEE	
Memory Impairment	Health				TEXT, ORAL;		
Migraine	Professional				20 MG, SEE		
Multiple Drug Overdose	Other				TEXT; 40 MG,		
Mydriasis					BID, ORAL		
Nausea		Xanax(Alprazolam)	SS				
Night Sweats		Cocaine(Cocaine)	SS				
Pain		Marijuana(Cannabis)	SS				
Pain In Extremity		Neurontin					
Pulmonary Congestion		(Gabapentin)	C				
Refusal Of Treatment By Patient		Flexeril					
Respiratory Arrest		(Cyclobenzaprine					
Respiratory Depression		Hydrochloride)	C				
Respiratory Distress		Doxepin (Doxepin)	C				
Respiratory Rate		Remeron(Mirtazapine)	C				
Decreased		Trazodone(Trazodone)	C				
Sedation		Ambien(Zolpidem					
Sinusitis		Tartrate)	C				
Tremor		Zanaflex(Tizanidine					
Ulcer		Hydrochloride)	C				
Vision Blurred		Clonidine(Clonidine)	C				
Vomiting		Klonopin(Clonazepam)	C				
		Atarax(Hydroxyzine					
		Hydrochloride)	C				
		Ativan(Lorazepam)	C				
		Vicodin	C				
		Inderal(Propranolol					
		Hydrochloride)	C				
		Ultram	C				
		Naprosyn (Naproxen)	C				
		Valium (Diazepam)	C				
		Risperdal					
		(Risperidone)	C				
		Depakote(Valproate					
		Semisodium)	C				
		Thiamine (Thiamine)	C				
		Mellaril					
		(Thioridazine					
		Hydrochloride)	C				
		Imitrex (Sumatriptan					
		Succinate)	C				

Lithium (Lithium) C  
 Seroquel  
 (Quetiapine) C  
 Cogentin  
 (Benzatropine  
 Mesilate) C  
 Tylenol W/Codeine  
 No. 3 C  
 Albuterol  
 (Salbutamol) C  
 Haldol (Haloperidol) C  
 Imitrex "Glaxo"  
 (Sumatriptan) C  
 Librium "Hoffman"  
 (Chlordiazepoxide  
 Hydrochloride) C  
 Atenolol (Atenolol) C

21-Jul-2006 10:28 AM

Page: 65

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Percocet C  
 Prozac (Fluoxetine  
 Hydrochloride) C  
 Maxalt (Rizatriptan  
 Benzoate) C  
 Skelaxin  
 (Metaxalone) C  
 Antivert (Nicotinic  
 Acid, Meclozine  
 Hydrochloride) C  
 Trimox (Amoxicillin  
 Trihydrate) C  
 Ranitidine  
 (Ranitidine) C  
 Nexium  
 (Esomeprazole) C  
 Combivent  
 (Ipratropium  
 Bromide, Salbutamol  
 Sulfate) C

Date:10/30/03ISR Number: 4223935-1Report Type:Expedited (15-DaCompany Report #KII-2003-0004043

Age:19 YR Gender:Male I/FU:1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Aggression Alcohol Use Aspiration Body Temperature Increased Convulsion Depressed Level Of	Health Professional	Oxycontin Tablets (Oxycodone Hydrochloride) Cr Tablet	PS		ORAL	20 MG, SEE TEXT, ORAL	
		Soma (Carisoprodol)		SS		ORAL	SEE TEXT, ORAL	



Alcohol (Ethanol) SS

Date:10/30/03ISR Number: 4224207-1Report Type:Expedited (15-DaCompany Report #OXYT000085

Age:23 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Literature	Roxicodone					
	Drug Abuser	Health	(Oxycodone Hcl)	PS				
	Multiple Drug Overdose	Professional	Alprazolam					
		(Alprazolam)	SS					
		Marijuana (Cannabis)	SS					

Date:10/31/03ISR Number: 4224883-3Report Type:Expedited (15-DaCompany Report #KII-2003-0003984

Age:24 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Aggression	Health	Oxycontin Cr	PS				
Initial or Prolonged	Depressed Level Of	Professional	Xanax(Alprazolam)	SS				
Other	Consciousness	Other	Ibuprofen(Ibuprofen)	SS				
	Hypertension		Alcohol(Ethanol)	SS				
	Multiple Drug Overdose		Marijuana(Cannabis)	SS				
	Sinus Tachycardia		Tricyclic					
	Supraventricular		Antidepressants()	SS				
	Tachycardia		Acetaminophen(Acetam					
	Toxicologic Test Abnormal		inophen)	SS				

Date:10/31/03ISR Number: 4224987-5Report Type:Expedited (15-DaCompany Report #USA-2003-0007583

Age:54 YR Gender:Male I/FU:F

Outcome	PT
Death	Arteriosclerosis
	Arteriosclerosis Coronary
	Artery
	Cardiomegaly
	Coronary Artery Occlusion
	Hepatic Fibrosis

21-Jul-2006 10:28 AM

Page: 67

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hepatic Steatosis								
Hepatomegaly								
Hypertension		Health	Oxycodone					
Pancreatitis Acute		Professional	Hydrochloride					
Pancreatitis Chronic		Other	(Similar To Nda					
Pulmonary Oedema			20-553)(Oxycodone					
Toxicologic Test Abnormal			Hydrochloride)	PS				
Ventricular Hypertrophy			Hydrocodone					
			Bitartrate (Similar					
			To Ind					



59,175)(Hydrocodone  
 Bitartrate, SS  
 Methadone(Methadone) SS  
 Diazepam(Diazepam) SS  
 Cannabis(Cannabis) SS  
 Oxazepam(Oxazepam) SS  
 Temazepam(Temazepam) SS  
 Promethazine(Prometh  
 azine) SS  
 Acetaminophen(Parace  
 tamol) SS

Date:10/31/03ISR Number: 4225320-5Report Type:Expedited (15-DaCompany Report #USA-2003-0009582

Age:53 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Morphine Sulfate					
Other	Arteriosclerosis	Professional	(Similar To Nda					
	Bronchitis	Other	19-516) (Morphine					
	Bronchopneumonia		Sulfate)	PS				
	Cardiomegaly		Darvon					
	Depressed Level Of		(Dextropropoxyphene					
	Consciousness		Hydrochloride)	SS				
	Drug Abuser		Percocet					
	Drug Toxicity		(Paracetamol,					
	Intracardiac Thrombus		Oxycodone					
	Multiple Drug Overdose		Hydrochloride)	SS				
	Pulmonary Congestion		Cannabis (Cannabis)	SS				
	Pulmonary Oedema		Acetaminophen					
	Snoring		(Paracetamol)	SS				
			Fioricet					
			(Bupropion)	C				
			Ativan (Lorazepam)	C				
			Celexa (Citalopram					
			Hydrobromide)	C				
			Vicodin	C				
			Zocor "Merck"					
			(Simvastatin)	C				
			Atenolol (Atenolol)	C				
			Tricor (Fenofibrate)	C				
			Mirapex "Boehringer					
			Ingelheim"					
			(Pramipexole					
			Dihydrochloride)	C				
			Nortriptyline					
			(Nortriptyline)	C				
			Nicoderm (Nicotine)	C				

Date:11/03/03ISR Number: 4226803-4Report Type:Expedited (15-DaCompany Report #2003-DE-05245GD

Age:26 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Literature	Methadone					
	Intentional Drug Misuse		(Methadone)	PS				
			Chlordiazepoxide					
			(Chlordiazepoxide)	SS				
			Marijuana (Cannabis)	SS				

Date:11/03/03ISR Number: 4227094-0Report Type:Expedited (15-DaCompany Report #2003-DE-05098GD

Age:20 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Abuser	Literature	Methadone					
	Overdose		(Methadone)	PS		RT		
			Marijuana (Cannabis)	SS		RT		

Date:11/03/03ISR Number: 4227097-6Report Type:Expedited (15-DaCompany Report #2003-DE-05103GD

Age:52 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Literature	Methadone					
	Drug Abuser		(Methadone)	PS	ORAL	PO		
	Overdose		Marijuana (Cannabis)	SS		IH		
	Respiratory Arrest							

Date:11/04/03ISR Number: 4227104-0Report Type:Expedited (15-DaCompany Report #USA-2003-0005884

Age:34 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization -	Accidental Overdose
Initial or Prolonged	Agitation
Other	Alcohol Withdrawal Syndrome
	Anxiety
	Arthralgia
	Asthenia
	Asthma
	Bipolar Disorder
	Blood Glucose Decreased
	Blood Glucose Increased
	Blood Prolactin Increased
	Bronchitis
	Chills
	Depressed Level Of Consciousness
	Depression
	Dizziness
	Drug Abuser
	Drug Dependence
	Drug Withdrawal Syndrome
	Dysarthria
	Dyspnoea
	Dysuria
	Feeling Jittery

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Adverse Event	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Gastroenteritis							
Hallucination, Auditory							
Headache	Consumer	Oxycontin Tablets					
Heart Rate Increased	Health	(Oxycodone					
Hyperhidrosis	Professional	Hydrochloride)Cr					
Hypertension	Other	Tablet	PS		ORAL		SEE IMAGE
Lethargy		Xanax(Alprazolam)	SS				
Logorrhoea		Cocaine(Cocaine)	SS				
Lymphadenopathy		Marijuana(Cannabis)	SS				
Migraine		Neurontin					
Multiple Drug Overdose		(Gabapentin)	C				
Mydriasis		Flexeril					
Nausea		(Cyclobenzaprine					
Neck Pain		Hydrochloride)	C				
Night Sweats		Doxepin (Doxepin)	C				
Pain		Remeron					
Pain		(Mirtazapine)	C				
Pyrexia		Trazodone					
Respiratory Rate		(Trazodone)	C				
Decreased		Ambien (Zolpidem					
Respiratory Tract		Tartrate)	C				
Congestion		Zanaflex (Tizanidine					
Sedation		Hydrochloride)	C				
Self-Medication		Clonidine					
Sinusitis		(Clonidine)	C				
Swollen Tongue		Klonopin					
Thirst		(Clonazepam)	C				
Vision Blurred		Atarax (Hydroxyzine					
		Hydrochloride)	C				
		Ativan (Lorazepam)	C				
		Vicodin	C				
		Inderal (Propranolol					
		Hydrochloride)	C				
		Ultram	C				
		Naprosyn (Naproxen)	C				
		Valium (Diazepam)	C				
		Risperdal					
		(Risperidone)	C				
		Depakote (Valproate					
		Semisodium)	C				
		Thiamine (Thiamine)	C				
		Mellaril					
		(Thioridazine					
		Hydrochloride)	C				
		Imitrex (Sumatriptan					
		Succinate)	C				

Lithium (Lithium) C  
 Seroquel  
 (Quetiapine) C  
 Cogentin  
 (Benzatropine  
 Mesilate) C  
 Tylenol W/Codeine  
 No. 3 C  
 Albuterol  
 (Salbutamol) C  
 Haldol (Haloperidol) C  
 Imitrex "Glaxo"  
 (Sumatriptan) C  
 "Hoffman"

21-Jul-2006 10:28 AM

Page: 70

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

(Chlordiazepoxide  
 Hydrochloride) C  
 Atenolol (Atenolol) C  
 Percocet C  
 Prozac (Fluoxetine  
 Hydrochloride) C  
 Maxalt (Rizatriptan  
 Benzoate) C  
 Skelaxin  
 (Metaxalone) C  
 Antivert (Nicotinic  
 Acid, Meclozine  
 Hydrochloride) C  
 Trimox (Amoxicillin  
 Trihydrate) C  
 Ranitidine  
 (Ranitidine) C  
 Nexium  
 (Esomeprazole) C  
 Combivent  
 (Ipratropium  
 Bromide, Salbutamol  
 Sulfate) C

Date:11/06/03ISR Number: 4230303-5Report Type:Expedited (15-DaCompany Report #USA-2003-0007123

Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Brain Herniation	Health	Oxycodone					
	Brain Oedema	Professional	Hydrochloride					
	Bronchopneumonia	Other	(Similar To Nda					
	Cardiomegaly		20-553)(Oxycodone					
	Congestive Cardiomyopathy		Hydrochloride)	PS				
	Drug Toxicity		Ethanol (Ethanol)	SS				
	Hepatic Congestion		Cannabis (Cannabis)	SS				
	Multiple Drug Overdose							

Pulmonary Congestion  
Pulmonary Oedema

Date:11/07/03ISR Number: 4229938-5Report Type:Periodic Company Report #US-GLAXOSMITHKLINE-A0390037A Age:16 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Disorientation	Consumer	Wellbutrin	PS	Glaxosmithkline	ORAL		
	Dissociation		Marijuana	SS	UNKNOWN			
	Flat Affect							
	Panic Attack							
	Paranoia							

Date:11/12/03ISR Number: 4234627-7Report Type:Expedited (15-DaCompany Report #USA-2003-0009898 Age:31 YR Gender:Male I/FU:I

Outcome	PT
Death	Accidental Overdose
	Arteriosclerosis
	Foreign Body Aspiration
	Lung Abscess
	Multiple Drug Overdose
	Pulmonary Congestion

21-Jul-2006 10:28 AM

Page: 71

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Respiratory Depression

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Consumer	Oxycontin					
Health	Tablets(Oxycodone					
Professional	Hydrochloride) Cr					
Other	Tablet	PS				
	Methadone(Methadone)	SS				
	Diazepam(Diazepam)	SS				
	Marijuana(Cannabis)	SS				

Date:11/13/03ISR Number: 4235853-3Report Type:Expedited (15-DaCompany Report #USA-2003-0005884 Age:34 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization -	Accidental Overdose
Initial or Prolonged	Agitation
Other	Alcohol Withdrawal
	Syndrome
	Anxiety
	Arthralgia
	Asthenia
	Asthma
	Bipolar I Disorder

Blood Glucose Decreased  
 Blood Glucose Increased  
 Blood Prolactin Increased  
 Bronchitis  
 Chills  
 Depressed Level Of  
 Consciousness  
 Depression  
 Dizziness  
 Drug Abuser  
 Drug Dependence  
 Drug Withdrawal Syndrome  
 Dysarthria  
 Dyspnoea  
 Dysuria  
 Feeling Jittery  
 Feeling Of Despair  
 Formication  
 Galactorrhoea  
 Gastroenteritis  
 Hallucination  
 Hallucination, Auditory  
 Headache  
 Heart Rate Increased  
 Hyperhidrosis  
 Hypertension  
 Irritability  
 Lethargy  
 Logorrhoea  
 Lymphadenopathy  
 Mania  
 Migraine  
 Multiple Drug Overdose  
 Mydriasis  
 Nausea  
 Night Sweats

21-Jul-2006 10:28 AM

Page: 72

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Pain	Consumer	Oxycontin Tablets					
Paraesthesia Oral							
Psychomotor Hyperactivity							
Pulmonary Congestion	Other	(Oxycodone Hydrochloride)	PS		SEE IMAGE,		
Pyrexia				ORAL			
Respiratory Rate Decreased				ORAL			
Sedation		Xanax (Alprazolam)	SS				
Sinusitis		Cocaine(Cocaine)	SS				
Thirst		Marijuana(Cannabis)	SS				
Tremor		Neurontin					
Vision Blurred		(Gabapentin)	C				
		Flexeril					
		(Cyclobenzaprine)					

Hydrochloride) C  
Doxepin (Doxepin) C  
Remeron  
(Mirtazapine) C  
Trazodone  
(Trazodone) C  
Ambien (Zolpidem  
Tartrate) C  
Zanaflex (Tizanidine  
Hydrochloride) C  
Clonidine  
(Clonidine) C  
Klonopin  
(Clonazepam) C  
Atarax (Hydroxyzine  
Hydrochloride) C  
Ativan (Lorazepam) C  
Vicodin C  
Inderal (Propranolol  
Hydrochloride) C  
Ultram C  
Naprosyn (Naproxen) C  
Valium (Diazepam) C  
Risperdal  
(Risperidone) C  
Depakote (Valproate  
Semisodium) C  
Thiamine (Thiamine) C  
Mellaril  
(Thioridazine  
Hydrochloride) C  
Imitrex (Sumatriptan  
Succinate) C  
Lithium (Lithium) C  
Seroquel  
(Quetiapine) C  
Cogentin  
(Benzatropine  
Mesilate) C  
Tylenol W/Codeine  
No. 3 C  
Albuterol  
(Salbutamol) C  
Haldol (Haloperidol)  
Tablet C  
Imitrex "Glaxo"  
(Sumatriptan) C

Atenolol (Atenolol) C  
 Percocet C  
 Prozac (Fluoxetine Hydrochloride) C  
 Maxalt (Rizatriptan Benzoate) C  
 Skelaxin (Metaxalone) C  
 Antivert (Nicotinic Acid, Meclozine Hydrochloride) C  
 Trimox (Amoxicillin Trihydrate) C  
 Ranitidine (Ranitidine) C  
 Nexium (Esomeprazole) C  
 Combivent (Ipratropium Bromide, Salbutamol Sulfate) C

Date:11/24/03ISR Number: 4241166-6Report Type:Expedited (15-DaCompany Report #2003-03798

Age:33 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Literature Health Professional	Diphenhydramine Hydrochloride) (Diphenhydramine Hydrochloride) Fiorinal 50/325/40 (Watson Laboratories (Caffeinen 40 Mg, Aspirin 325 Mg, Butalbital 50 Mg) Marijuana (Cannabis)	PS	Watson Laboratories			

Date:11/24/03ISR Number: 4241222-2Report Type:Expedited (15-DaCompany Report #2003-03866

Age:28 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Literature Health Professional	Diazepam (Watson Laboratories) (Diazepam) Tablet Gamma Hydroxybutyrate() Marijuana(Cannabis)	PS	Watson Laboratories			

Date:11/25/03ISR Number: 4242090-5Report Type:Expedited (15-DaCompany Report #2003-04041

Age:23 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source
Death	Cardio-Respiratory Arrest	Literature Health



FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Professional

Product	Role	Manufacturer	Route	Dose	Duration
Alprazolam (Watson Laboratories)	PS	Watson Laboratories			
(Alprazolam) Tablet					
Oxycodone Hydrochloride/Apap					
Unknown Strength & Formulation (Waston)					
(Oxycodone SS		Waston Laboratories			
Marijuana (Cannabis0	SS				

Date:11/25/03ISR Number: 4242139-XReport Type:Expedited (15-DaCompany Report #2003-04106 Age:15 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Literature	Tramadol (Watson Laboratories)	PS	Watson Laboratories			
	Health Professional	Heroin (Diamorphine)	SS					
		Marijuana (Cannabis)	SS					

Date:11/25/03ISR Number: 4242250-3Report Type:Expedited (15-DaCompany Report #2003-03986 Age:26 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Literature	Chlordiazepoxide					
	Health Professional	Hydrochloride (Watson Laboratories)	(Chlordiazepoxide)	PS				
		Methadone (Methadone)	SS					
		Marijuana (Cannabis)	SS					

Date:11/25/03ISR Number: 4242514-3Report Type:Expedited (15-DaCompany Report #03P-163-0240845-00 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Literature	Hydrocodone/Acetaminophen (Vicodin)					
	Intentional Drug Misuse	Health Professional	(Hydrocodone/Acetaminophen)	PS		ORAL	ORAL	
		Cannabis	SS			RESPIRATORY (INHALATION)	INHALATION	

Outcome PT  
 Required Caesarean Section  
 Intervention to Complications Of Maternal  
 Prevent Permanent Exposure To Therapeutic  
 Impairment/Damage Drugs  
 Drug Abuser  
 Intentional Self-Injury

21-Jul-2006 10:28 AM

Page: 75

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Pregnancy

Psychotic Disorder

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Foreign Health Professional Other	Seroquel	PS		ORAL	600 MG DAILY	
Professional Other	Chlorpromazine	SS		ORAL	200 MG DAILY	
Other	Folic Acid	SS		ORAL	400 UG DAILY	
	Cannabis	SS		PO		
	Amphetamine	SS				

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Foreign Health Professional Other	Seroquel	PS		TRANSPLACENTAL	600 MG DAILY	
Professional Other	Chlorpromazine	SS		TPL	200 MG DAILY	
Other	Folic Acid	SS		TPL	400 UG DAILY	
	Cannabis	SS		TPL		
	Amphetamine	SS				

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Consumer Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-553) (Oxycodone Hydrochloride)	PS		ORAL	ORAL	
	Diazepam (Diazepam)	SS				
	Oxazepam (Oxazepam)	SS				
	Temazepam					

(Temazepam) SS  
 Lorazepam  
 (Lorazepam) SS  
 Cannabnoids  
 (Cannabis) SS  
 Diphenhydramine  
 Hydrochloride  
 (Diphenhydramine  
 Hydrochloride) SS  
 Gabapentin  
 (Gabapentin) SS  
 Claritin  
 (Loratadine) C  
 Zoloft (Sertraline  
 Hydrochloride) C  
 Altace (Ramipril) C  
 Allopurinol  
 (Allopurinol) C  
 Depakote (Valproate  
 Semisodium) C  
 Soma (Carisoprodol) C  
 Relafen (Nabumetone) C

21-Jul-2006 10:28 AM

Page: 76

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/02/03ISR Number: 4246476-4Report Type:Expedited (15-DaCompany Report #100127

Age:22 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Aggression Anxiety Respiratory Arrest	Health Professional	Testosterone Marijuana	PS SS		INTRAMUSCULAR IM		1 ML WEEKLY

Date:12/02/03ISR Number: 4246986-XReport Type:Expedited (15-DaCompany Report #USA-2003-0011021

Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose Bronchial Oedema Bronchospasm Drug Toxicity Inflammation Multiple Drug Overdose Muscle Hypertrophy Pulmonary Congestion Pulmonary Oedema	Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-553) (Oxycodone Hydrochloride) Alprazolam (Alprazolam) Marijuana (Cannabis) Caffeine (Caffeine) Nicotine (Nicotine)	PS SS SS SS				

Date:12/02/03ISR Number: 4246989-5Report Type:Expedited (15-DaCompany Report #USA-2003-0011022

Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Alcohol Poisoning	Health	Oxycontin Tablets					
	Cardiomegaly	Professional	(Oxycodone					
	Drug Abuser	Other	Hydrochloride) Cr					
	Haemorrhage	Subcutaneous	Tablet	PS			20 MG	
	Hypertensive Heart		Ethanol (Ethanol)	SS				
	Disease		Meprobamate					
	Pulmonary Congestion		(Meprobamate)	SS				
	Pulmonary Oedema		Marijuana (Cannabis)	SS				
	Ventricular Hypertrophy							

Date:12/03/03ISR Number: 4246815-4Report Type:Expedited (15-DaCompany Report #USA-2003-0010937

Age:36 YR Gender:Male I/FU:I

Outcome	PT
Death	Aortic Injury
	Cardio-Respiratory Arrest
	Contusion
	Drug Screen Positive
	Emphysema
	Excoriation
	Fracture
	Haemothorax
	Injury
	Intracranial Injury
	Laceration
	Peritoneal Haemorrhage
	Road Traffic Accident
	Splenic Injury

21-Jul-2006 10:28 AM

Page: 77

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Subarachnoid Haemorrhage

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Health	Oxycodone					
Professional	Hydrochloride					
Other	(Similar To Nda					
	20-553)(Oxycodone					
	Hydrochloride)	PS				
	Cocaine (Cocaine)	SS				
	Methadone					
	(Methadone)	SS				
	Marijuana (Cannibas)	SS				

Date:12/04/03ISR Number: 4247022-1Report Type:Expedited (15-DaCompany Report #USA-2003-0011065

Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Alcohol Use Injury Toxicologic Test Abnormal	Health Professional Other	Oxycodone Hydrochloride(Similar To Nda 20-553)(Oxycodone Hydrochloride) PS Marijuana (Cannabis)Unknown SS Ethanol (Ethanol) Unknown SS					

Date:12/08/03ISR Number: 4249292-2Report Type:Expedited (15-DaCompany Report #USA-2003-0005884

Age:34 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged Other	Accidental Overdose Agitation Alcohol Withdrawal Syndrome Anxiety Arthralgia Asthenia Asthma Bipolar I Disorder Blood Glucose Decreased Blood Glucose Increased Blood Prolactin Increased Bronchitis Chills Depressed Level Of Consciousness Depression Dizziness Drug Abuser Drug Dependence Drug Withdrawal Syndrome Dysarthria Dysphagia Dyspnoea Dysuria Feeling Jittery Feeling Of Despair Formication

21-Jul-2006 10:28 AM

Page: 78

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Outcome	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Galactorrhoea Gastroenteritis Hallucination, Auditory Headache Heart Rate Increased Hyperhidrosis	Consumer Health Professional	Oxycontin Tablets (Oxycodone Hydrochloride) Cr					

Hypertension	Other	Tablet	PS	ORAL	80 MG, SEE
Irritability				TEXT, ORAL	
Lethargy		Xanax (Alprazolam)	SS		
Logorrhoea		Cocaine (Cocaine)	SS		
Lymphadenopathy		Marijuana (Cannabis)	SS		
Mania		Neurontin			
Migraine		(Gabapentin)	C		
Multiple Drug Overdose		Flexeril			
Muscle Spasms		(Cyclobenzaprine			
Mydriasis		Hydrochloride)	C		
Nausea		Doxepin (Doxepin)	C		
Neck Pain		Remeron			
Night Sweats		(Mirtazapine)	C		
Pain		Trazodone			
Paraesthesia Oral		(Trazodone)	C		
Pharyngolaryngeal Pain		Ambien (Zolpidem			
Psychomotor Hyperactivity		Tartrate)	C		
Pulmonary Congestion		Zanaflex (Tizanidine			
Pupils Unequal		Hydrochloride)	C		
Pyrexia		Clonidine			
Respiratory Rate		(Clonidine)	C		
Decreased		Klonopin			
Sedation		(Clonazepam)	C		
Sinusitis		Atarax (Hydroxyzine			
Thirst		Hydrochloride)	C		
Vision Blurred		Ativan (Lorazepam)	C		
		Vicodin	C		
		Inderal (Propranolol			
		Hydrochloride)	C		
		Ultram	C		
		Naprosyn (Naproxen)	C		
		Valium (Diazepam)	C		
		Risperdal			
		(Risperidone)	C		
		Depakote (Valproate			
		Semisodium)	C		
		Thiamine (Thiamine)	C		
		Mellaril			
		(Thioridazine			
		Hydrochloride)	C		
		Imitrex (Sumatriptan			
		Succinate)	C		
		Lithium (Lithium)	C		
		Seroquel			
		(Quetiapine)	C		
		Cogentin			
		(Benzatropine			
		Mesilate)	C		
		Tylenol W/Codine No.			
		3	C		
		Albuterol			
		(Salbutamol)	C		
		Haldol (Haloperidol)			
		Tablet	C		
		Imitrex "Glaxo"			

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

(Sumatriptan) C  
 Librium "Hoffman"  
 (Chlordiazepoxide  
 Hydrochloride)  
 Tablet C  
 Atenolol (Atenolol)  
 Tablet C  
 Percocet C  
 Prozac (Fluoxetine  
 Hydrochloride) C  
 Maxalt (Rizatriptan  
 Benzoate) C  
 Skelaxin  
 (Metaxalone) C  
 Antivert (Nicotinic  
 Acid, Meclozine  
 Hydrochloride) C  
 Trimox (Amoxicillin  
 Trihydrate) C  
 Ranitidine  
 (Ranitidine) C  
 Nexium  
 (Esomeprazole) C  
 Combivent  
 (Ipratropium  
 Bromide, Salbutamol  
 Sulfate) C  
 Tegretol  
 (Carbamazepine) C

Date:12/12/03ISR Number: 4251614-3Report Type:Expedited (15-DaCompany Report #USA-2003-0009495

Age:20 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Brain Oedema	Consumer	Oxycontin					
	Cardio-Respiratory Arrest	Health	Tablets(Oxycodone					
	Coma	Professional	Hydrochloride) Cr					
	Drug Toxicity	Other	Tablet PS					
	Obesity		Methadone					
	Overdose		(Methadone) Cr					
	Pulmonary Congestion		Tablet SS					
	Pulmonary Oedema		Nicotine (Nicotine) SS					
	Splenomegaly		Cannabis (Cannabis) SS					
	Thyroid Neoplasm							
	Toxicologic Test Abnormal							
	Ventricular Hypertrophy							
	Vomiting							

Date:12/15/03ISR Number: 4251629-5Report Type:Expedited (15-DaCompany Report #SE-ROCHE-242745

Age:23 YR Gender:Male I/FU:F

Outcome PT

Other Amnesia  
 Antisocial Personality  
 Disorder  
 Delusional Perception  
 Dissociative Disorder  
 Drug Abuser  
 Fatigue  
 Hallucination, Auditory

21-Jul-2006 10:28 AM

Page: 80

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Homicide								
Memory Impairment								
Narcissistic Personality Disorder		Valium	PS	Roche	UNKNOWN			
Paranoia		Flunitrazepam	SS	Roche	ORAL			
Therapeutic Agent Toxicity		Flunitrazepam	SS	Roche	ORAL			
Thinking Abnormal		Amphetamine	SS		UNKNOWN			
		Cannabis	SS		RESPIRATORY			
				(INHALATION)				
		Alcohol	SS		ORAL			

Date:12/16/03ISR Number: 4253569-4Report Type:Expedited (15-DaCompany Report #USA-2003-0011365 Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Cr	PS				
	Homicide	Other	Marijuana(Cannabis)	SS				

Date:12/17/03ISR Number: 4256696-0Report Type:Periodic Company Report #USA-2003-0006358 Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Consumer	Oxycontin Tablets					
Other	Depersonalisation	Health	(Oxycodone					
	Drug Abuser	Professional	Hydrochloride)	PS		ORAL	ORAL	
	Dyspepsia	Other	Carisoprodol					
	Epistaxis		(Carisoprodol)	SS				
	Insomnia		Cocaine (Cocaine)	SS				
	Multiple Drug Overdose		Carbamazepine					
	Respiratory Depression		(Carbamazepine)	SS				
			Meprobamate					
			(Meprobamate)	SS				
			Diazepam (Diazepam)	SS				
			Temazepam					
			(Temazepam)	SS				
			Acetaminophen					
			W/Hydrocodone					
			Bitartrate					
			(Paracetamol,					
			Hydrocodone	SS				



Oxazepam (Oxazepam) SS  
Cannabis (Cannabis) SS  
Alprazolam SS  
Hydromorphone  
(Hydromorphone) SS

Date:12/17/03ISR Number: 4256771-0Report Type:Periodic Company Report #USA-2003-0006760 Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Consumer	Oxycontin Tablets					
Other	Drug Abuser	Health Professional Other	(Oxycodone Hydrochloride)	PS		ORAL ORAL	20 MG, TID,	
			Nicotine (Nicotine)	SS				
			Acetaminophen (Acetaminophen)	SS				
			Marijuana (Cannabis)	SS				

21-Jul-2006 10:28 AM

Page: 81

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Ethanol (Ethanol) SS  
Prilosec C  
Prozac C  
Alprazolam C

Date:12/17/03ISR Number: 4267748-3Report Type:Periodic Company Report #USA-2003-0007617 Age:16 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-553) (Oxycodone Hydrochloride)	PS				
			Morphine Sulfate (Similar To Nda 19-516) (Morphine Sulfate)	SS				
			Cocaine (Cocaine)	SS				
			Quinine (Quinine)	SS				
			Caffeine (Caffeine)	SS				
			Nicotine (Nicotine)	SS				
			Codeine (Codeine)	SS				
			Cannabis (Cannabis)	SS				
			Procaine (Procaine)	SS				

Date:12/17/03ISR Number: 4267823-3Report Type:Periodic Company Report #USA-2003-0007407

Age:22 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose Multiple Drug Overdose Other	Health Professional	Oxycontin Tablets (Oxycodone Hydrochloride) PS Cocaine (Cocaine) SS Citalopram (Citalopram) SS Diazepam (Diazepam) SS Temazepam (Temazepam) SS Cannabis (Cannabis) SS Nicotine (Nicotine) SS Valproic Acid (Valproic Acid) SS			MG,		

Date:12/17/03ISR Number: 4267825-7Report Type:Periodic Company Report #USA-2003-0007408 Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose Other	Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-553) (Oxycodone Hydrochloride) PS Cannabis (Cannabis) SS Alprazolam (Alprazolam) SS Diazepam (Diazepam) SS Temazepam					

21-Jul-2006 10:28 AM

Page: 82

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

(Temazepam) SS  
Oxazepam (Oxazepam) SS  
Nicotine (Nicotine) SS  
Caffeine (Caffeine) SS

Date:12/17/03ISR Number: 4267841-5Report Type:Periodic Company Report #USA-2003-0007422 Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Abuser Polysubstance Abuse	Other	Oxycodone Hydrochloride (Similar To Nda 20-553) (Oxycodone Hydrochloride) PS Ethanol (Ethanol) SS Diazepam (Diazepam) SS Alprazolam (Alprazolam) SS Temazepam (Temazepam) SS					

Acetaminophen  
(Acetaminophen) SS  
Cannabis (Cannabis) SS

Date:12/17/03ISR Number: 4267902-0Report Type:Periodic Company Report #USA-2003-0007748 Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Multiple Drug Overdose	Health Professional	Oxycodone Hydrochloride					
	Overdose	Other	(Similar To Nda 20-553) (Oxycodone Hydrochloride)					
			Morphine Sulfate (Similar To Nda 19-516) (Morphine Sulfate)					
			Cocaine (Cocaine)					
			Cannabis (Cannabis)					
			Methadone (Methadone)					

Date:12/17/03ISR Number: 4268343-2Report Type:Periodic Company Report #USA-2003-0009237 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride)					
			Ethanol (Ethanol)		ORAL	ORAL		
			Marijuana (Cannabis)					
			Cocaine (Cocaine)					

21-Jul-2006 10:28 AM

Page: 83

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/17/03ISR Number: 4268471-1Report Type:Periodic Company Report #USA-2003-0008838 Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride)					
			Marijuana (Cannabis)					

Date:12/17/03ISR Number: 4268473-5Report Type:Periodic Company Report #USA-2003-0008839 Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride)	PS				
			Marijuana (Cannabis)	SS				

Date:12/17/03ISR Number: 4268474-7Report Type:Periodic Company Report #USA-2003-0008840 Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride)	PS				
			Marijuana (Cannabis)	SS				

Date:12/17/03ISR Number: 4269067-8Report Type:Periodic Company Report #USA-2003-0007087 Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone Hydrochloride					
	Multiple Drug Overdose	Professional	(Similar To Nda 20-553) (Oxycodone Hydrochloride)	PS				
	Other		Alprazolam (Alprazolam)	SS				
			Caffeine (Caffeine)	SS				
			Ephedrine (Ephedrine)	SS				
			Acetaminophen (Paracetamol)	SS				
			Dextromethorphan (Dextromethorphan)	SS				
			Chlorpheniramine (Chlorphenamine)	SS				
			Levorphanol (Levorphanol)	SS				
			Marijuana (Cannabis)	SS				

Date:12/17/03ISR Number: 4269120-9Report Type:Periodic Company Report #USA-2003-0007058 Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone Hydrochloride					
		Professional	(Similar To Nda					
		Other						

20-553) PS  
 Carisoprodol SS  
 Meprobamate SS  
 Caffeine SS  
 Metoclopramide SS  
 Dextromethorphan SS  
 Ephedrine SS  
 Nicotine SS  
 Methsuximide SS  
 Cannabis SS

Date:12/17/03ISR Number: 4270183-5Report Type:Periodic Company Report #USA-2003-0006349 Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser Mental Impairment	Health Professional Company Representative	Oxycontin Tablets 20 Mg(Oxycodone Hydrochloride) Pcp (Phenobarbital, Codeine Phosphate, Phenaz) Marijuana (Cannabis)	PS SS SS			20 MG, Q12H	
						RESPIRATORY (INHALATION)	INHALATION	

Date:12/17/03ISR Number: 4270260-9Report Type:Periodic Company Report #2012756 Age:21 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Other	Accidental Overdose Drug Abuser	Consumer Health Professional Other	Oxycontin Tablets (Oxycodone Hydrochloride) Oxycodone Hydrochloride (Similar To Nda 20-553) (Oxycodone Hydrochloride) Xanax (Alprazolam) Marijuana (Cannabis) Alcohol (Ethanol) Lidocaine (Lidocaine) Nicotine (Nicotine)	PS SS SS SS SS SS SS			40 MG, Q12H 5 MG	

Date:12/17/03ISR Number: 4270262-2Report Type:Periodic Company Report #2012767 Age:16 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Other	Accidental Overdose Drug Abuser	Consumer Other	Oxycontin Tablets (Oxycodone Hydrochloride) Marijuana (Cannabis) Alcohol (Ethanol)	PS SS SS		ORAL INHALATION ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/17/03ISR Number: 4270334-2Report Type:Periodic Company Report #2015431 Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health Professional	Oxycodone Hydrochloride (Similar To Nda 20-553) Oxycodone Hydrochloride) PS Methadone (Methadone) SS Diazepam (Diazepam) SS Marijuana (Cannabis) SS					

Date:12/17/03ISR Number: 4270816-3Report Type:Periodic Company Report #USA-2003-0005841 Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose Loss Of Consciousness Multiple Drug Overdose Other	Consumer Health Professional	Oxycontin Tablets (Oxycodone Hydrochloride) PS Morphine Sulfate (Similar To Nda 19-516) (Morphine Sulfate) SS Cocaine (Cocaine) SS Diazepam (Diazepam) SS Xanax (Alprazolam) SS Marijuana (Cannabis) SS Lidocaine (Lidocaine) SS Caffeine (Caffeine) SS Temazepam (Temazepam) SS Codeine (Codeine) SS					

Date:12/17/03ISR Number: 4270891-6Report Type:Periodic Company Report #USA-2002-0000387 Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose Respiratory Depression	Consumer Health Professional Other	Oxycontin Tablets (Oxycodone Hydrochloride) PS			INTRAVENOUS INTRAVENOUS	UNK MG, UNK,	

Ethanol (Ethanol) SS  
 Diazepam (Diazepam) SS  
 Cannabis (Cannabis) SS  
 Phenothiazine  
 (Phenothiazine) SS  
 Caffeine (Caffeine) SS  
 Lidocaine  
 (Lidocaine) SS

Date:12/17/03ISR Number: 4270969-7Report Type:Periodic Company Report #USA-2002-0002869 Age:20 YR Gender:Male I/FU:I

Outcome PT Report Source  
 Death Accidental Overdose Health  
 Drug Abuser Professional

21-Jul-2006 10:28 AM

Page: 86

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Other

Product	Role	Manufacturer	Route	Dose	Duration
Oxycotin Tablets (Oxycodone Hydrochloride)	PS				
Alprazolam (Alprazolam)	SS				
Temazepam (Temazepam)	SS				
Canabanoids (Cannabis)	SS				
Diazepam (Diazepam)	SS				
Nicotine (Nicotine)	SS				
Caffeine (Caffeine)	SS				
Acetaminophen (Paracetamol)	SS				

Date:12/17/03ISR Number: 4271077-1Report Type:Periodic Company Report #KII-2003-0004053 Age:52 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Depressed Level Of Consciousness Multiple Drug Overdose Nodal Rhythm Somnolence	Health Professional	Oxycontin Tablets (Oxycodone Hydrochloride)	PS		ORAL ORAL	SEE TEXT,	
		Wellbutrin (Amfebutamone Hydrochloride)	SS		ORAL	ORAL	SEE TEXT,	
		Verapamil (Verapamil)	SS		ORAL	ORAL	SEE TEXT,	

Hydrochlorothiazide (Hydrochlorothiazide )	SS	ORAL	SEE TEXT, ORAL
Zoloft (Sertraline Hydrochloride)	SS	ORAL	SEE TEXT, ORAL
Neuroton (Citicoline Sodium)	SS	ORAL	SEE TEXT, ORAL
Tricyclic Antidepressants	SS	ORAL	ORAL
Cannabis (Cannabis)	SS		

Date:12/17/03ISR Number: 4271168-5Report Type:Periodic Company Report #KII-2003-0003745 Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Coma Respiratory Arrest	Health Professional	Oxycontin Tablets (Oxycodone Hydrochloride)			ORAL	ORAL	
			Darvocet-N (Paracetamol)	SS				
			Alcohol (Ethanol)	SS				
			Marijuana (Cannabis)	SS				
			Barbiturates	SS				

21-Jul-2006 10:28 AM

Page: 87

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/17/03ISR Number: 4271173-9Report Type:Periodic Company Report #USA-2003-0005850 Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Aggression Drug Dependence	Consumer Other	Oxycontin Tablets (Oxycodone Hydrochloride)					
			Xanax (Alprazolam)	SS				
			Methadone (Methadone)	SS				
			Marijuana (Cannabis)	SS				
			Heroin (Diamorphine)	SS				

Date:12/17/03ISR Number: 4271177-6Report Type:Periodic Company Report #USA-2003-0005876 Age:39 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser Judgement Impaired	Consumer Other	Oxycontin Tablets (Oxycodone Hydrochloride)					
			Heroin (Diamorphine)	SS				
			Marijuana (Cannabis)	SS				



Date:12/17/03ISR Number: 4271184-3Report Type:Periodic Company Report #USA-2003-0008950 Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Abuser	Consumer	Oxycontin Tablets					
Other	Multiple Drug Overdose	Other	(Oxycodone Hydrochloride)	PS		INTRAVENOUS		INTRAVENOUS
			Valium (Diazepam)	SS		INTRAVENOUS		INT (CONT)
			Xanax (Alprazolam)	SS		INTRAVENOUS		INT (CONT)
			Marijuana (Cannabis)	SS				

Date:12/17/03ISR Number: 4271243-5Report Type:Periodic Company Report #USA-2002-0000143 Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda 20-553) (Oxycodone Hydrochloride)	PS				
			Alprazolam	SS				
			Diazepam (Diazepam)	SS				
			Trazodone					
			(Trazodone)	SS				
			Marijuana (Cannabis)	SS				

Date:12/17/03ISR Number: 4271890-0Report Type:Periodic Company Report #KII-2002-0000263 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Multiple Drug Overdose	Health	Oxycontin Tablets					
Hospitalization - Initial or Prolonged		Professional	(Oxycodone Hydrochloride)	PS				
		Company Representative	Hydrocodone					

21-Jul-2006 10:28 AM

Page: 88

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Bitartrate (Similar To Ind 59,175) (Hydrocodone Bitartrate) SS  
Valium (Diazepam) SS  
Soma (Carisoprodol) SS  
Xanax (Alprazolam) SS  
Cocaine (Cocaine) SS  
Marijuana (Cannabis) SS

Date:12/17/03ISR Number: 4272003-1Report Type:Periodic Company Report #USA-2003-0009899 Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Intentional Overdose Multiple Drug Overdose	Consumer Health Professional Other	Oxycontin Tablets (Oxycodone Hydrochloride) PS Benadryl (Diphenhydramine Hydrochloride) SS Methadone (Methadone) SS Alcohol (Ethanol) SS Marijuana (Cannabis) SS					

Date:12/17/03ISR Number: 4272056-0Report Type:Periodic Company Report #KII-2002-0002424 Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Multiple Drug Overdose Somnolence	Health Professional	Oxycodone Hydrochloride (Similar To Nda 20-553) (Oxycodone Hydrochloride) PS Acetaminophen (Paracetamol) SS Acetylsalicylic Acid (Acetylsalicylic Acid) SS Marijuana (Cannabis) SS Benzodiazepine Derivatives SS			ORAL ORAL		

Date:12/17/03ISR Number: 4272234-0Report Type:Periodic Company Report #KII-2001-0002337 Age:18 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Multiple Drug Overdose	Health Professional Company Representative	Oxycontin Tablets (Oxycodone Hydrochloride) PS Pcp (Phenobarbital, Codeine Phosphate, Phenaz) SS Cannabis (Cannabis) SS Alcohol (Ethanol) SS					

21-Jul-2006 10:28 AM

Page: 89

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/17/03ISR Number: 4272319-9Report Type:Periodic Company Report #KII-2001-0000410 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Abuser	Health	Oxycontin Tablets					
	Multiple Drug Overdose	Professional	(Oxycodone				80 MG, SEE	
		Company Representative	Hydrochloride)	PS			TEXT,	
			Marijuana (Cannabis)	SS				

Date:12/17/03ISR Number: 4272366-7Report Type:Periodic Company Report #KII-2002-0004106 Age:40 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Accidental Overdose Agitation	Health Professional	Oxycontin Tablets (Oxycodone Hydrochloride)	PS				
	Alanine Aminotransferase Increased		Morphine Sulfate (Similar To Nda					
	Aspartate Aminotransferase Increased		19-516) (Morphine Sulfate)	SS				
	Body Temperature Increased		Soma (Carisoprodol)	SS				
	Heart Rate Increased		Ativan (Lorazepam)	SS				
	Lethargy		Elavil (Amitriptyline					
	Multiple Drug Overdose		Hydrochloride)	SS				
	Psychotic Disorder		Acetylsalicylic Acid (Acetylsalicylic Acid)	SS				
			Acetaminophen (Paracetamol)	SS				
			Cannabis (Cannabis)	SS				

Date:12/17/03ISR Number: 4272368-0Report Type:Periodic Company Report #USA-2003-0009691 Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Dependence	Consumer	Oxycontin Tablets					
Other	Multiple Drug Overdose	Other	(Oxycodone Hydrochloride)	PS				
			Cocaine (Cocaine)	SS				
			Cannabis (Cannabis)	SS				
			Antidepressants	SS				

Date:12/17/03ISR Number: 4272472-7Report Type:Periodic Company Report #KII-2002-0001988 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycodone					
	Malaise	Health	Hydrochloride					
	Tachycardia	Professional	(Similar To Nda					
		20-553)	PS		ORAL	ORAL		
			Marijuana (Cannabis)	SS		INHALATION		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/17/03ISR Number: 4272740-9Report Type:Periodic Company Report #USA-2002-0002752 Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Consumer	Oxycontin Tablets					
	Dyspnoea	Health	(Oxycodone	PS				
	Vomiting	Professional	Hydrochloride)					
		Other	Ethanol (Ethanol)	SS	ORAL	ORAL		
			Cannabis (Cannabis)	SS				
			Oxymorphone					
			(Oxymorphone)	SS				
			Benzodiazepine					
			Derivatives	SS				
			Caffeine (Caffeine)	SS				
			Nicotine (Nicotine)	SS				

Date:12/17/03ISR Number: 4272796-3Report Type:Periodic Company Report #USA-2003-0008974 Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone					
			Hydrochloride)	PS		UNK MG,		
			Marijuana					
			(Cannabis)	SS				
			Alcohol (Ethanol)	SS				

Date:12/17/03ISR Number: 4273591-1Report Type:Periodic Company Report #USA-2002-0000690 Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Consumer	Oxycontin Tablets					
Other	Drug Abuser	Health	(Oxycodone	PS				
	Pain	Professional	Hydrochloride)		ORAL		20 MG, SEE	
	Respiratory Depression	Other					TEXT, ORAL	
	Weight Increased		Marijuana (Cannabis)	SS				
			Phencyclidine					
			(Phencyclidine)	SS				
			Tylox	C				
			Lortab	C				
			Cipro	C				
			Tuss-Ionex	C				
			Neurontin	C				
			Norco	C				

Date:12/17/03ISR Number: 4274258-6Report Type:Periodic Company Report #USA-2003-0007255 Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda					
			20-553) Oxycodone					
			Hydrochloride)				PS	
			Alprazolam					
			(Alprazolam)				SS	
			Methadone					
			(Methadone)				SS	
			Caffeine (Caffeine)				SS	

21-Jul-2006 10:28 AM

Page: 91

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Nicotine (Nicotine) SS  
 Acetaminophen  
 (Paracetamol) SS  
 Cocaine (Cocaine) SS  
 Marijuana (Cannabis) SS

Date:12/17/03ISR Number: 4275196-5Report Type:Periodic Company Report #USA-2003-0009143 Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Consumer	Oxycodone					
	Multiple Drug Overdose	Health	Hydrochloride					
		Professional	(Similar To Nda					
		Other	20-553) (Oxyc				PS	
			Diazepam (Diazepam)				SS	
			Tamazepam					
			(Tamazepam)				SS	
			Cannabis (Cannabis)				SS	
			Caffeine (Caffeine)				SS	
			Nicotine (Nicotine)				SS	
			Morphine Sulfate					
			(Similar To Nda					
			19-516) (Morphine					
			Sulfate)				SS	
			Celexa				C	

Date:12/18/03ISR Number: 4255750-7Report Type:Expedited (15-DaCompany Report #USA-2003-0005884 Age:34 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization -	Accidental Overdose
Initial or Prolonged	Agitation
Other	Anxiety
	Arthralgia
	Asthenia

Asthma  
 Bipolar I Disorder  
 Blood Glucose Decreased  
 Blood Glucose Increased  
 Blood Prolactin  
 Bronchitis  
 Chills  
 Depressed Level Of  
 Consciousness  
 Depression  
 Dizziness  
 Drug Abuser  
 Drug Dependence  
 Drug Withdrawal Syndrome  
 Dysarthria  
 Dyspnoea  
 Dysuria  
 Feeling Abnormal  
 Feeling Jittery  
 Formication  
 Galactorrhoea  
 Gastroenteritis  
 Hallucination, Auditory  
 Heart Rate Increased

21-Jul-2006 10:28 AM

Page: 92

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Adverse Event	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hyperhidrosis							
Hypertension							
Lethargy	Consumer	Oxycontin Tablets					
Logorrhoea	Health	(Oxycodone					
Lymphadenopathy	Professional	Hydrochloride) Cr					
Migraine	Other	Tablet	PS				SEE IMAGE
Multiple Drug Overdose							
Mydriasis		Xanax (Alprazolam)	SS				
Nausea		Cocaine (Cocaine)	SS				
Night Sweats		Marijuana (Cannabis)	SS				
Pain		Neurontin					
Paraesthesia Oral		(Gabapentin)	C				
Pyrexia		Flexeril					
Respiratory Rate		(Cyclobenzaprine					
Decreased		Hydrochloride)	C				
Respiratory Tract		Doxepin (Doxepin)	C				
Congestion		Remeron					
Sedation		(Mirtazapine)	C				
Sinusitis		Trazodone					
Thirst		(Trazodone)	C				
Treatment Noncompliance		Ambien (Zolpidem					
Tremor		Tartrate)	C				
Vision Blurred		Zanaflex (Tizanidine					
		Hydrochloride)	C				
		Clonidine					
		(Clonidine)	C				

Klonopin  
(Clonazepam) C  
Atarax (Hydroxyzine  
Hydrochloride) C  
Ativan (Lorazepam) C  
Vicodin C  
Inderal (Propranolol  
Hydrochloride) C  
Ultram C  
Naprosyn (Naproxen) C  
Valium (Diazepam) C  
Risperdal  
(Risperidone) C  
Depakote (Valproate  
Semisodium) C  
Thiamine (Thiamine) C  
Mellaril  
(Thioridazine  
Hydrochloride) C  
Imitrex (Sumatriptan  
Succinate) C  
Lithium (Lithium) C  
Seroquel  
(Quetiapine) C  
Cogentin  
(Benzatropine  
Mesilate) C  
Tylenol W/Codeine  
No. 3 C  
Albuterol  
(Salbutamol) C  
Haldol (Haloperidol)  
Tablet C  
Imitrex "Glaxo"  
(Sumatriptan) C

21-Jul-2006 10:28 AM

Page: 93

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Librium "Hoffman"  
(Chlordiazepoxide  
Hydrochloride)  
Tablet C  
Atenolol (Atenolol)  
Tablet C  
Percocet C  
Prozac (Fluoxetine  
Hydrochloride) C  
Maxalt (Rizatriptan  
Benzoate) C  
Skelaxin  
(Metaxalone) C  
Antivert (Nicotinic  
Acid, Meclozine

Hydrochloride) C  
 Trimox (Amoxicillin  
 Trihydrate) C  
 Ranitidine  
 (Ranitidine) C  
 Nexium  
 (Esomeprazole) C  
 Combivent  
 (Ipratropium  
 Bromide, Salbutamol  
 Sulfate) C  
 Tegretol  
 (Carbamazeine) C

Date:12/18/03ISR Number: 4256099-9Report Type:Expedited (15-DaCompany Report #USA-2003-0011866 Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Screen Positive Pulmonary Oedema	Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-553)(Oxycodone Hydrochloride)	PS				
			Diazepam (Diazepam)	SS				
			Valproic Acid/Valproic Acid)	SS				
			Mirtazapine (Mirtazapine)	SS				
			Topiramate (Topiramate)	SS				
			Marijuana (Cannabis)	SS				

Date:01/05/04ISR Number: 4264816-7Report Type:Expedited (15-DaCompany Report #OXCD20030013 Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Life-Threatening	Multiple Drug Overdose	Literature Health Professional	Oxycodone Methadone Doxepin	PS SS				
			Diazepam	SS				
			Marijuana	SS				

21-Jul-2006 10:28 AM

Page: 94

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/05/04ISR Number: 4264872-6Report Type:Expedited (15-DaCompany Report #OXCD20030018 Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Coma	Literature	Oxycodone	PS				



Overdose Health Alprazolam SS  
 Pulmonary Oedema Professional Marijuana SS

Date:01/07/04ISR Number: 4267097-3Report Type:Expedited (15-DaCompany Report #2012272

Age:42 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Consumer	Oxycontin					
Hospitalization - Initial or Prolonged	Back Pain Drug Abuser	Health Professional	Tablets(Oxycodone Oxycontin					
Other	Haematemesis Headache Respiratory Arrest	Other	Tablets(Oxycodone Hydrochloride) Cr PS Diazepam (Diazepam) SS Oxazepam (Oxazepam) SS Temazepam (Temazepam) SS Lorazepam (Lorazepam) SS Cannabnoids (Cannabis) SS Diphenhydramine Hydrochloride (Diphenhydramine Hydrochloride) SS Gabapentin (Gabapentin) SS Claritin (Loratadine) C Zoloft (Sertraline Hydrochloride) C Altace (Ramipril) C Allopurinol (Allopurinol) C Depakote (Valproate Semisodium) C Soma (Carisoprodol) C Relafen (Nabumetone) C			SEE IMAGE		

Date:01/07/04ISR Number: 4267104-8Report Type:Expedited (15-DaCompany Report #USA-2003-0005884

Age:34 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Accidental Overdose Agitation
Other	Alcohol Withdrawal Syndrome Anxiety Arthralgia Asthenia Asthma Bipolar I Disorder Blood Glucose Decreased Blood Glucose Increased Blood Prolactin Increased Bronchitis

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Chills	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Depressed Level Of Consciousness	Consumer	Oxycontin Tablets					
Depression	Health	(Oxycodone					
Dizziness	Professional	Hydrochloride) Cr					
Drug Abuser	Other	Tablet	PS		SEE IMAGE		
Drug Dependence		Xanax (Alprazolam)	SS				
Drug Withdrawal Syndrome		Cocaine (Cocaine)	SS				
Duodenitis		Marijuana (Cannabis)	SS				
Dysarthria		Neurontin					
Dyspnoea		(Gabapentin)	C				
Dysuria		Flexeril					
Feeling Jittery		(Cyclobenzaprine					
Feeling Of Despair		Hydrochloride)	C				
Formication		Doxepin (Doxepin)	C				
Galactorrhoea		Remeron					
Gastritis		(Mirtazapine)	C				
Gastroenteritis		Trazodone					
Hallucination, Auditory		(Trazodone)	C				
Headache		Ambien (Zolpidem					
Heart Rate Increased		Tartrate)	C				
Hyperhidrosis		Zanaflex (Tizanidine					
Hypertension		Hydrochloride)	C				
Lethargy		Clonidine					
Logorrhoea		(Clonidine)	C				
Lymphadenopathy		Klonopin					
Migraine		(Clonazepam)	C				
Multiple Drug Overdose		Atarax (Hydroxyzine					
Mydriasis		Hydrochloride)	C				
Nausea		Ativan (Lorazepam)	C				
Neck Pain		Vicodin	C				
Night Sweats		Inderal (Propranolol					
Pain		Hydrochloride)	C				
Paraesthesia Oral		Ultram	C				
Pulmonary Congestion		Naprosyn (Naproxen)	C				
Pyrexia		Valium (Diazepam)	C				
Respiratory Rate Decreased		Risperdal					
Sedation		(Risperidone)	C				
Sinusitis		Depakote (Valproate					
Thirst		Semisodium)	C				
Vision Blurred		Thiamine (Thiamine)	C				
		Mellaril					
		(Thioridazine					
		Hydrochloride)	C				
		Imitrex (Sumatriptan					
		Succinate)	C				
		Lithium (Lithium)	C				
		Seroquel					
		(Quetiapine)	C				
		Cogentin					

(Benzatropine  
Mesilate) C  
Tylenol W/Codeine  
No. 3 C  
Albuterol  
(Salbutamol) C  
Haldol (Haloperidol)  
Tablet C  
Imitrex "Glaxo"  
(Sumatriptan) C

21-Jul-2006 10:28 AM

Page: 96

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Librium "Hoffman"  
(Chlordiazepoxide  
Hydrochloride)  
Tablet C  
Atenolol (Atenolol)  
Tablet C  
Percocet C  
Prozac (Fluoxetine  
Hydrochloride) C  
Maxalt (Rizatriptan  
Benzoate) C  
Skelaxin  
(Metaxalone) C  
Antivert (Nicotinic  
Acid, Meclozine  
Hydrochloride) C  
Trimox (Amoxicillin  
Trihydrate) C  
Ranitidine  
(Ranitidine) C  
Nexium  
(Esomeprazole) C  
Combivent  
(Ipratropium  
Bromide, Salbutamol  
Sulfate) C  
Tegretol  
(Carbamazepine) C  
Protonix  
(Pantoprazole) C

Date:01/13/04ISR Number: 4269757-7Report Type:Expedited (15-DaCompany Report #WAES 0308USA02600

Age:43 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Agitation		Stromectol	PS	Merck & Co., Inc	ORAL	1	DAY
Hospitalization -	Coma		Alcohol	SS		ORAL	1	DAY
Initial or Prolonged	Filariasis		Alcohol	SS		ORAL	1	DAY
	Headache		Cannabis	SS		ORAL	1	DAY

Palpitations  
Vertigo Cannabis SS ORAL 1 DAY

Date:01/20/04ISR Number: 4277037-9Report Type:Expedited (15-DaCompany Report #GBWYE509414JAN04

Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Optic Neuropathy Photopsia	Health Professional Other	Advil (Ibuprofen, Tablet,0) Cannabis (Cannabis) Combivir (Lamivudine/Zidovudine) Viramune (Nevirapine) Vioxx (Rofecoxib) Salbutamol (Salbutamol)	PS SS SS SS C C				
						ORAL	450 MG 2X PER 1 DAY ORAL	
						ORAL	400 MG 1X PER 1 DAY ORAL	

21-Jul-2006 10:28 AM

Page: 97

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Seretide  
(Salmeterol/Fluticasone) C  
Unspecified  
Antidepressant  
(Unspecified  
Antidepressant) C

Date:01/22/04ISR Number: 4278860-7Report Type:Expedited (15-DaCompany Report #USA-2003-0005884

Age:34 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged Other	Accidental Overdose Agitation Alcohol Withdrawal Syndrome Alcoholism Anxiety Arthralgia Asthenia Asthma Bipolar I Disorder Blood Glucose Decreased Blood Glucose Increased Blood Prolactin Increased Bronchitis Chills Depressed Level Of

Consciousness  
 Depression  
 Dizziness  
 Drug Abuser  
 Drug Dependence  
 Drug Withdrawal Syndrome  
 Duodenitis  
 Dysarthria  
 Dyspnoea  
 Dysuria  
 Feeling Jittery  
 Feeling Of Despair  
 Fibromyalgia  
 Formication  
 Galactorrhoea  
 Gastritis  
 Gastroenteritis  
 Hallucination, Auditory  
 Headache  
 Heart Rate Increased  
 Hyperhidrosis  
 Hypertension  
 Lethargy  
 Logorrhoea  
 Lymphadenopathy  
 Migraine  
 Multiple Drug Overdose  
 Mydriasis  
 Nausea  
 Neck Pain  
 Night Sweats  
 Pain

21-Jul-2006 10:28 AM

Page: 98

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Adverse Event	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Paraesthesia Oral							
Pulmonary Congestion							
Pyrexia	Consumer	Oxycontin Tablets					
Respiratory Rate Decreased	Other	(Oxycodone Hydrochloride) Cr Tablet	PS		SEE IMAGE		
Sedation		Xanax (Alprazolam)	SS				
Self-Medication		Cocaine (Cocaine)	SS				
Sinusitis		Marijuana (Cannabis)	SS				
Thirst		Neurontin (Gabapentin)	C				
Treatment Noncompliance		Flexeril (Cyclobenzaprine Hydrochloride)	C				
Vision Blurred		Doxepin (Doxepin)	C				
		Remeron (Mirtazapine)	C				

Trazodone  
(Trazodone) C  
Ambien (Zolpidem  
Tartrate) C  
Zanaflex (Tizanidine  
Hydrochloride) C  
Clonidine  
(Clonidine) C  
Klonopin  
(Clonazepam) C  
Atarax (Hydroxyzine  
Hydrochloride) C  
Ativan (Lorazepam) C  
Vicodin C  
Inderal (Propranolol  
Hydrochloride) C  
Ultram C  
Naprosyn (Naproxen) C  
Valium (Diazepam) C  
Risperdal  
(Risperidone) C  
Depakote (Valproate  
Semisodium) C  
Thiamine (Thiamine) C  
Mellaril  
(Thioridazine  
Hydrochloride) C  
Initrex (Sumatriptan  
Succinati) C  
Lithium (Lithium) C  
Seroquel  
(Quetiapine) C  
Cogentin  
(Benzatropine  
Mesilate) C  
Tylenol W/Codeine  
No. 3 C  
Albuterol  
(Salbutamol) C  
Haldol (Haloperidol) C  
Imitrex "Glaxo"  
(Sumatriptan) C  
Librium "Hoffman"

21-Jul-2006 10:28 AM

Page: 99

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

(Chlordiazepoxide  
Hydrochloride) C  
Atenolol (Atenolol) C  
Percocet C  
Prozac (Fluoxetine  
Hydrochloride) C  
Maxalt (Rizatriptan  
Benzoate) C

Skelaxin  
 (Metaxalone) C  
 Antivert (Nicotinic  
 Acid, Meclozine  
 Hydrochloride) C  
 Trimox (Amoxicillin  
 Trihydrate) C  
 Ranitidine  
 (Ranitidine) C  
 Nexium  
 (Esomeprazole) C  
 Combivent  
 (Ipratropium  
 Bromide, Salbutamol  
 Sulfate) C  
 Tegretol  
 (Carbamazepine) C  
 Protonix  
 (Pantoprazole) C

Date:01/22/04ISR Number: 4278865-6Report Type:Expedited (15-DaCompany Report #2012272

Age:42 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Consumer	Oxycontin Tablets					
Hospitalization -	Apnoea	Health	(Oxycodone					
Initial or Prolonged	Back Pain	Professional	Hydrochloride) Cr					
Other	Drug Abuser	Other	Tablet PS			SEE IMAGE		
	Haematemesis		Diazepam (Diazepam)	SS				
	Headache		Oxazepam (Oxazepam)	SS				
	Polysubstance Abuse		Temazepam					
			(Temazepam)	SS				
			Lorazepam					
			(Lorazepam)	SS				
			Cannabis (Cannabis)	SS				
			Diphenhydramine					
			Hydrochloride					
			(Diphenhydramine					
			Hydrochloride)	SS				
			Gabapentin					
			(Gabapentin)	SS				
			Claritin					
			(Loratadine)	C				
			Zoloft (Sertraline					
			Hydrochloride)	C				
			Altace (Ramipril)	C				
			Allopurinol					
			(Allopurinol)	C				
			Depakote (Valproate					
			Semisodium)	C				
			Soma (Carisoprodol)	C				

Freedom Of Information (FOI) Report

Date:01/26/04ISR Number: 4280339-3Report Type:Expedited (15-DaCompany Report #2003-UK-00522UK

Age:43 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Optic Neuropathy	Foreign Health Professional Other	Nevirapine (Eu/1/97/055/002) PS Combivir (Nevirapine) SS			ORAL	SEE IMAGE	
			Ibuprofen (Ibuprofen) SS				300 MG	
			Cannabis (Cannabis) SS					
			Vioxx (Rofecoxib) C					
			Salbutamol (Salbutamol) C					
			Seretide C					
			Antidepressant C					

Date:02/05/04ISR Number: 4286939-9Report Type:Expedited (15-DaCompany Report #2012272

Age:42 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accident	Consumer	Oxycontin Tablets (Oxycodone)					
Hospitalization - Initial or Prolonged	Accidental Overdose Back Pain	Health Professional	Hydrochloride) Cr					
Other	Drug Abuser	Other	Tablet PS			SEE IMAGE		
	Drug Toxicity		Diazepam (Diazepam) SS					
	Haematemesis		Oxazepam (Oxazepam) SS					
	Headache		Temazepam (Temazepam) SS					
	Neck Pain		Lorazepam (Lorazepam) SS					
			Cannabnoids (Cannabis) SS					
			Diphenhydramine Hydrochloride (Diphenhydramine Hydrochloride) SS					
			Gabapentin (Gabapentin) SS					
			Claritin (Loratadine) C					
			Zoloft (Sertraline Hydrochloride) C					
			Altace (Ramipril) C					
			Allopurinol (Allopurinol) C					
			Depakote (Valproate Semisodium) C					
			Soma (Carisoprodol) C					
			Relafen (Nabumetone) C					



Outcome PT  
 Hospitalization - Blood Potassium Decreased  
 Initial or Prolonged Blood Pressure Diastolic  
 Other Decreased  
 Drug Screen Positive

21-Jul-2006 10:28 AM

Page: 101

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Heart Rate Increased  
 Intentional Overdose

Outcome	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Lethargy	Study	Oxycodone					
Miosis	Health	Hydrochloride					
Multiple Drug Overdose	Professional	(Similar To Nda					
Oxygen Saturation	Other	20-553) (Oxycodone					
Decreased		Hydrochloride)	PS				
Pruritus		Benzodiazepine					
Somnolence		Derivatives	SS				
		Marijuana (Cannabis)	SS				
		Cocaine (Cocaine)	SS				

Outcome	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Health	Adderall					
Abnormal Behaviour	Professional	Xr(Amphetamine					
Drug Abuser		Aspartate,					
Hallucination		Amphetamine Sulfate,					
Legal Problem		Dextroamphetamine	PS		ORAL	30 MG DAILY,	
Psychotic Disorder					ORAL		
Thinking Abnormal		Valium					
		/Net/(Diazepam)	SS				
		Unspecified Pain					
		Medication()	SS				
		Marijuana(Marijuana)	SS				

Outcome	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Study	Morphine Sulfate					
Initial or Prolonged	Health	(Similar To Nda					
Other	Professional	19-516)(Morphine					
Depressed Level Of	Other	Sulfate)Unknown	PS		ORAL	15, ORAL	
Consciousness		Morphine Sulfate					
Haemoglobin Decreased		(Similar To Nda					
Headache		19-516) (Morphine					
Heart Rate Increased		Sulfate) Other	SS		ORAL	15, ORAL	
Hypotension							

Multiple Drug Overdose  
Respiratory Depression  
Somnolence

Marijuana (Cannabis) SS  
Tricyclic  
Antidepressants() SS  
Baclofen (Baclofen) C  
Furosemide  
(Furosemide) C  
Antihyperlipidemic C  
Proton Pump  
Inhibitor C  
Lisinopril  
(Lisinopril) C  
Piroxicam  
(Piroxicam) C

21-Jul-2006 10:28 AM

Page: 102

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/19/04ISR Number: 4301303-1Report Type:Expedited (15-DaCompany Report #USA-2003-0009433

Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Delusion Depressed Mood Disturbance In Attention	Consumer Other	Oxycontin Tablets (Oxycodone Hydrochloride) Cr Tablet PS			ORAL ORAL	20 MG, BID,	
	Drug Dependence Drug Ineffective Drug Withdrawal Syndrome Hallucination, Auditory Insomnia Memory Impairment Pain Paranoia Polysubstance Abuse Psychotic Disorder Schizophrenia, Paranoid Type Weight Decreased		Alcohol(Ethanol) Marijuana(Cannabis) Cocaine (Cocaine) Norco Xanax (Alprazolam)	SS SS SS C C				

Date:02/20/04ISR Number: 4302411-1Report Type:Expedited (15-DaCompany Report #B0320324A

Age:25 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Bradycardia Circulatory Collapse Complications Of Maternal Exposure To Therapeutic Drugs Foetal Disorder	Foreign Health Professional	Emgel (Erythromycin) (Formulation Unknown) Cannabis (Formuation Unknown) (Cannabis) Betamethasone	PS SS		ORAL	2/ORAL	

Hypokalaemia	(Formulation			
Hypomagnesaemia	Unknown)			
Maternal Therapy To	(Betamethasone)	SS	INTRAMUSCULAR	12 MG/ PER
Enhance Foetal Lung			DAY/	
Maturity			INTRAMUSCULAR	
Muscular Weakness	Ferrous Sulfate	C		
Premature Baby	Sandocal	C		
Renal Tubular Acidosis	Folic Acid	C		

Date:02/24/04ISR Number: 4304278-4Report Type:Expedited (15-DaCompany Report #USA-2003-0007661

Age:53 YR Gender:Male I/FU:F

Outcome PT  
 Death Accident At Work  
 Arteriosclerosis  
 Asphyxia  
 Brain Oedema  
 Cardiomegaly  
 Contusion  
 Drug Level Above  
 Therapeutic  
 Excoriation  
 Extradural Haematoma  
 Head Injury  
 Hepatic Congestion  
 Laceration  
 Pharyngeal Haemorrhage  
 Pulmonary Congestion

21-Jul-2006 10:28 AM

Page: 103

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Renal Disorder							
Soft Tissue Haemorrhage							
Spinal Fracture	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Health	Oxycodone					
	Professional	Hdyrochloride					
	Other	(Similar To Nda					
		20-553)(Oxycodone					
		Hydrochloride)	PS				
		Hydrocodone					
		Bitartrate (Similar					
		To Ind 59,175)					
		(Hydrocodone					
		Bitartrate) Unknown	SS				
		Alprazolam					
		(Alprazolam)	SS				
		Cannabis (Caqnabis)	SS				
		Acetaminophen					
		(Paracetamol)	SS				
		Ethanol (Ethanol)	SS				

Date:02/27/04ISR Number: 4308727-7Report Type:Expedited (15-DaCompany Report #USA-2003-0011315

Age:50 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Morphine Sulfate					
	Cerebral Haemorrhage	Professional	(Similar To Nda					
	Coma	Other	19-516)(Morphine					
	Drug Screen Positive		Sulfate) Unknown	PS				
	Drug Toxicity		Hydroxyzine					
	Hypertensive Heart		(Hydroxyzine)	SS				
	Disease		Carisoprodol					
	Somnolence		(Carisoprodol)	SS				
			Nicotine (Nicotine)	SS				
			Cannabis (Cannabis)	SS				
			Temazepam					
			(Temazepam)	SS				
			Bupropion					
			(Amfebutamone)	SS				

Date:03/01/04ISR Number: 4309131-8Report Type:Expedited (15-DaCompany Report #USA-2003-0011570

Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycontin Tablets					
	Arteriosclerosis Coronary	Professional	(Oxycodone					
	Artery	Other	Hydrochloride) Cr					
	Cardiomegaly		Tablet	PS				
	Coma		Methadone					
	Hepatic Congestion		(Methadone)	SS				
	Hypertensive Heart		Valium (Diazepam)	SS				
	Disease		Ethanol (Ethanol)	SS				
	Multiple Drug Overdose		Ephedrine					
	Pulmonary Congestion		(Ephedrine)	SS				
	Spleen Congestion		Pseudoephedrine					
	Toxicologic Test Abnormal		(Pseudoephedrine)	SS				
			Meprobamate					
			(Meprobamate)	SS				
			Oxazepam (Oxazepam)	SS				
			Temazepam					

21-Jul-2006 10:28 AM

Page: 104

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

(Temazepam) SS  
 Cannabis (Cannabis) SS  
 Caffeine (Caffeine) SS  
 Nicotine (Nicotine) SS

Date:03/02/04ISR Number: 4311034-XReport Type:Expedited (15-DaCompany Report #KII-2003-0007398

Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abnormal Behaviour	Study	Morphine Sulfate					

Initial or Prolonged	Abscess	Health	(Similar To Nda		
Other	Acid Base Balance	Professional	19-516)(Morphine		
	Abnormal	Other	Sulfate) Unknown	PS	
	Agitation		Clonidine		
	Bradycardia		(Clonidine)	SS	ORAL ORAL
	Coma		Amfetamine		
	Electrocardiogram Pr		(Amfetamine)	SS	
	Shortened		Cannabis (Cannabis)	SS	
	Electrocardiogram Qrs		Promethazine		
	Complex Prolonged		(Promethazine)	C	
	Electrocardiogram Qt		Klonopin		
	Prolonged		(Clonazepam)	C	
	Local Swelling				
	Overdose				
	Pco2 Abnormal				
	Ph Body Fluid Abnormal				
	Respiratory Rate				
	Increased				
	Torsade De Pointes				
	Ventricular Tachycardia				
	Wolff-Parkinson-White				
	Syndrome				

Date:03/03/04ISR Number: 4312130-3Report Type:Expedited (15-DaCompany Report #USA-2003-0005884

Age:34 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization -	Abdominal Pain Upper
Initial or Prolonged	Accidental Overdose
Other	Agitation
	Alcohol Withdrawal
	Syndrome
	Anxiety
	Arthralgia
	Asthenia
	Asthma
	Bipolar I Disorder
	Blood Glucose Decreased
	Blood Glucose Increased
	Blood Prolactin Increased
	Bronchitis
	Chills
	Depressed Level Of
	Consciousness
	Depression
	Dizziness
	Drug Abuser
	Drug Dependence
	Drug Withdrawal Syndrome
	Duodenitis

21-Jul-2006 10:28 AM

Page: 105

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Dysarthria							
Dyspnoea							
Dysuria	Consumer	Oxycontin Tablets					
Feeling Jittery	Health	(Oxycodone					
Feeling Of Despair	Professional	Hydrochloride) Cr					
Formication	Other	Tablet	PS		ORAL	80 MG, SEE	
Galactorrhoea					TEXT, ORAL;		
Gastritis					20 MG, SEE		
Gastroenteritis					TEXT,		
Hallucination, Auditory					UNKNOWN; 40		
Headache		Xanax (Alprazolam)	SS				
Heart Rate Increased		Cocaine (Cocaine)	SS				
Hyperhidrosis		Marijuana (Cannabis)	SS				
Hypertension		Neurontin					
Lethargy		(Gabapentin)	C				
Logorrhoea		Flexeril					
Lymphadenopathy		(Cyclobenzaprine					
Migraine		Hydrochloride)	C				
Multiple Drug Overdose		Doxepin (Doxepin)	C				
Mydriasis		Remeron					
Nausea		(Mirtazapine)	C				
Neck Pain		Trazodone					
Night Sweats		(Trazodone)	C				
Pain		Ambien (Zolpidem					
Paraesthesia Oral		Tartrate)	C				
Pulmonary Congestion		Zanaflex (Tizanidine					
Pyrexia		Hydrochloride)	C				
Respiratory Rate		Clonidine					
Decreased		(Clonidine)	C				
Sedation		Klonopin					
Self-Medication		(Clonazepam)	C				
Sinusitis		Atarax (Hydroxyzine					
Thirst		Hydrochloride)	C				
Vision Blurred		Ativan (Lorazepam)	C				
		Vicodin	C				
		Inderal (Propranolol					
		Hydrochloride)	C				
		Ultram	C				
		Naprosyn (Naproxen)	C				
		Valium (Diazepam)	C				
		Risperdal					
		(Risperidone)	C				
		Depakote(Valproate					
		Semisodium)	C				
		Thiamine (Thiamine)	C				
		Mellaril					
		(Thioridazine					
		Hydrochloride)	C				
		Imitrex (Sumatriptan					
		Succinate)	C				
		Lithium (Lithium)	C				
		Seroquel					
		(Quetiapine)	C				
		Cogentin					
		(Benzatropine					
		Mesilate)	C				

Tylenol W/Codeine  
 No. 3 C  
 Albuterol  
 (Salbutamol) C

21-Jul-2006 10:28 AM

Page: 106

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Haldol (Haloperidol) C  
 Imitrex "Glaxo"  
 (Sumatriptan) C  
 Librium "Hoffman"  
 (Chlordiazepoxide  
 Hydrochloride) C  
 Atenolol (Atenolol) C  
 Percocet C  
 Prozac (Fluoxetine  
 Hydrochloride) C  
 Maxalt (Rizatriptan  
 Benzoate) C  
 Skelaxin  
 (Metaxalone) C  
 Antivert (Nicotinic  
 Acid, Meclozine  
 Hydrochloride) C  
 Trimox (Amoxicillin  
 Trihydrate) C  
 Ranitidine  
 (Ranitidine) C  
 Nexium  
 (Esomeprazole) C  
 Combivent  
 (Ipratropium  
 Bromide, Salbutamol  
 Sulfate) C  
 Tegretol  
 (Carbamazepine) C  
 Protonix  
 (Pantoprazole) C

Date:03/23/04ISR Number: 4325892-6Report Type:Expedited (15-DaCompany Report #2012272

Age:42 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Consumer	Oxycontin					
Hospitalization - Initial or Prolonged	Asthenia Back Pain	Health Professional	Tablets(Oxycodon Hydrochloride) Cr					
Other	Drug Abuser Drug Toxicity Headache Iron Deficiency Anaemia Mallory-Weiss Syndrome Neck Pain	Other	Tablet Diazepam(Diazepam) Oxazepam(Oxazepam) Temazepam(Temazepam) Lorazepam(Lorazepam)	PS SS SS SS	MG	10 & 20 & 40		

Respiratory Arrest  
Tachycardia

Cannabnoids(Cannabis ) SS  
Diphenhydramine Hydrochloride(Diphenhydramine Hydrochloride) SS  
Gabapentin(Gabapentin) SS  
Claritin(Loratadine) C  
Zoloft (Sertraline Hydrochloride) C  
Altace(Ramipril) C  
Allopurinol (Allopurinol) C  
Depakote (Valproate

21-Jul-2006 10:28 AM

Page: 107

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Semisodium) C  
Soma (Carisoprodol) C  
Relafen (Nabumetone) C

Date:03/23/04ISR Number: 4326399-2Report Type:Expedited (15-DaCompany Report #KII-2004-0008047 Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Ph Decreased	Study	Oxycontin Tablets					
	Coma	Health	(Oxycodone					
	Drug Abuser	Professional	Hydrochloride) Cr					
	Drug Screen Positive	Other	Tablet	PS		ORAL		ORAL
	Troponin Increased		Cocaine (Cocaine)	SS				
			Methocarbamol					
			(Methocarbamol)	SS		ORAL		ORAL
			Marijuana (Cannabis)	SS				

Date:03/29/04ISR Number: 4331431-6Report Type:Expedited (15-DaCompany Report #KII-2004-0008252 Age:33 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Anuria Blood Bicarbonate Abnormal Blood Calcium Decreased Blood Ph Abnormal Blood Phosphorus Increased Blood Urine Present Coma Confusional State Cough Dialysis Drug Abuser	Study Consumer Health Professional Other	Oxycontin Hydrochloride) (Oxycodone Hydrochloride) Cr Tablet Ethanol (Ethanol) Cannabis (Cannabis)					
				PS				
				SS				
				SS				



Drug Screen Positive  
 Dyspnoea  
 Haematocrit Decreased  
 Haemoglobin Decreased  
 Haemoptysis  
 Multiple Drug Overdose  
 Nausea  
 Renal Failure  
 Respiratory Rate  
 Increased  
 Sputum Abnormal  
 Urine Abnormality

Date:04/01/04ISR Number: 4333482-4Report Type:Expedited (15-DaCompany Report #KII-2003-0008869

Age:19 YR Gender:Male I/FU:I

Outcome PT  
 Hospitalization - Agitation  
 Initial or Prolonged Blood Creatinine  
 Other Increased  
 Coma  
 Cyanosis  
 Drug Screen Positive  
 Hypotension  
 Overdose

21-Jul-2006 10:28 AM

Page: 108

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Pulmonary Oedema  
 Vomiting

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Study	Morphine Sulfate					
Health	(Similar To Nda					
Professional	19-516)(Morphine					
Other	Sulfate) Unknwon	PS				
	Benzodiazepine					
	Derivaties	SS				
	Marijuana (Cannabis)	SS				
	Amfetamine					
	(Amfetamine)	C				
	Antidepressants	C				
	Ssri	C				

Date:04/02/04ISR Number: 4333670-7Report Type:Expedited (15-DaCompany Report #USA-2003-0005884

Age:34 YR Gender:Female I/FU:F

Outcome PT  
 Hospitalization - Abdominal Distension  
 Initial or Prolonged Abdominal Pain Upper  
 Other Accidental Overdose  
 Agitation

Anxiety  
 Arthralgia  
 Asthma  
 Back Pain  
 Bipolar I Disorder  
 Blood Glucose Decreased  
 Blood Glucose Increased  
 Blood Prolactin  
 Bronchitis  
 Chest Discomfort  
 Chest Pain  
 Chills  
 Dependence  
 Depressed Level Of  
 Consciousness  
 Depression  
 Dizziness  
 Drug Dependence  
 Drug Withdrawal Syndrome  
 Duodenitis  
 Dysarthria  
 Dyspepsia  
 Dyspnoea  
 Dysuria  
 Eructation  
 Feeling Jittery  
 Feeling Of Despair  
 Flatulence  
 Formication  
 Galactorrhoea  
 Gastritis  
 Hallucination, Auditory  
 Headache  
 Heart Rate Increased  
 Hypertension  
 Lethargy  
 Lipase Increased

21-Jul-2006 10:28 AM

Page: 109

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Adverse Event	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Logorrhoea							
Lymphadenopathy							
Medication Error	Consumer	Oxycontin Tablets					
Migraine	Health	(Oxycodone					
Mydriasis	Professional	Hydrochloride) Cr					
Night Sweats	Other	Tablet	PS	ORAL	SEE IMAGE		
Pain		Xanax (Alprazolam)	SS				
Pyrexia		Cocaine (Cocaine)	SS				
Respiratory Rate		Marijuana (Cannabis)	SS				
Decreased		Neurontin					
Respiratory Tract		(Gabapentin)	C				
Congestion		Flexeril					
Sedation							

Sinusitis	(Cyclobenzaprine	
Thirst	Hydrochloride)	C
Tongue Disorder	Doxepin (Doxepin)	C
Tremor	Remeron	
Vision Blurred	(Mirtazapine)	C
	Trazodone	
	(Trazodone)	C
	Ambien (Zolpidem	
	Tartrate)	C
	Zanaflex (Tizanidine	
	Hydrochloride)	C
	Clonidine	
	(Clonidine)	C
	Klonopin	
	(Clonazepam)	C
	Atarax (Hydroxyzine	
	Hydrochloride)	C
	Ativan (Lorazepam)	C
	Vicodin	C
	Inderal (Propranolol	
	Hydrochloride)	C
	Ultram	C
	Naprosyn (Naproxen)	C
	Valium (Diazepam)	C
	Risperdal	
	(Risperidone)	C
	Depakote (Valproate	
	Semisodium)	C
	Thiamine (Thiamine)	C
	Mellaril	
	(Thioridazine	
	Hydrochloride)	C
	Imitrex (Sumatriptan	
	Succinate)	C
	Lithium (Lithium)	C
	Seroquel	
	(Quetiapine)	C
	Cogentin	
	(Benzatropine	
	Mesilate)	C
	Tylenol W/Codeine	
	No. 3	C
	Albuterol	
	(Salbutamol)	C
	Haldol (Halopridol)	C
	Imitrex "Glaxo"	
	(Sumatriptan)	C
	Librium "Hoffman"	

Percocet C  
 Prozac (Fluoxetine  
 Hydrochloride) C  
 Maxalt (Rizatriptan  
 Benzoate) C  
 Skelaxin  
 (Metaxalone) C  
 Antivert (Nicotinic  
 Acid, Meclozine  
 Hydrochloride) C  
 Trimox (Amoxicillin  
 Trihydrate) C  
 Ranitidine  
 (Ranitidine) C  
 Nexium  
 (Esomeprazole) C  
 Combivent  
 (Ipratropium  
 Bromide, Salbutamol  
 Sulfate) C  
 Tegretol  
 (Carbamazepine) C  
 Protonix  
 (Pantoprazole) C

Date:04/07/04ISR Number: 4336427-6Report Type:Expedited (15-DaCompany Report #KII-2004-0009251 Age:26 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Alcohol Increased	Study	Oxycontin					
	Drug Abuser	Health	Tablets(Oxycodone					
	Drug Screen Positive	Professional	Hydrochloride) Cr					
	Loss Of Consciousness	Other	Tablet	PS				
	Medication Error		Benzodiazepine					
	Memory Impairment		Derivatives)	SS				
	Urinary Hesitation		Tetrahydrocannabinol					
			(Tetrahydrocannabino					
			l) SS					
			Alcohol (Ethanol)	SS				

Date:04/08/04ISR Number: 4336973-5Report Type:Expedited (15-DaCompany Report #2004020436 Age:26 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anxiety	Health	Benadryl					
	Headache	Professional	(Diphenhydramine)	PS		ORAL	50-75, 25 MG	
	Intentional Drug Misuse					TABS QD, ORAL		
	Overdose		Cannabis (Cannabis)	SS		RESPIRATORY		
	Restlessness					(INHALATION)	4-5 JOINTS	
	Tremor					QD,		
						INHALATION		
			Olanzapine					
			(Olanzapine)	C				
			Paroxetine					
			Hydrochloride					
			(Paroxetine)					

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/09/04ISR Number: 4338802-2Report Type:Expedited (15-DaCompany Report #USA-2003-0005884

Age:34 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization -	Abdominal Distension
Initial or Prolonged	Accidental Overdose
Other	Agitation
	Anxiety
	Arthralgia
	Asthma
	Bipolar I Disorder
	Blood Glucose Decreased
	Blood Glucose Increased
	Bronchitis
	Chest Pain
	Chills
	Confusional State
	Depressed Level Of Consciousness
	Depression
	Dizziness
	Drug Dependence
	Drug Withdrawal Syndrome
	Duodenitis
	Dysarthria
	Dyspepsia
	Dyspnoea
	Dysuria
	Eructation
	Feeling Jittery
	Feeling Of Despair
	Flatulence
	Formication
	Galactorrhoea
	Gallbladder Disorder
	Gastritis
	Hallucination
	Hallucination, Auditory
	Headache
	Heart Rate Increased
	Hypertension
	Lethargy
	Lipase Increased
	Logorrhoea
	Lymphadenopathy
	Mental Disorder
	Mental Status Changes
	Migraine
	Multiple Drug Overdose
	Mydriasis

Night Sweats  
Pain  
Paraesthesia Oral  
Respiratory Rate  
Decreased  
Respiratory Tract  
Congestion  
Sedation  
Sinusitis  
Thirst  
Tremor  
Ultrasound Scan Abnormal

21-Jul-2006 10:28 AM

Page: 112

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Vision Blurred

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Consumer Health Professional Other	Oxycontin Tablets (Oxycodone Hydrochloride) Cr Tablet PS			ORAL	80 MG, SEE TEXT, ORAL	
	Xanax (Alprazolam)	SS				
	Cocaine(Cocaine)	SS				
	Marijuana(Cannabis)	SS				
	Neurontin (Gabapentin)	C				
	Flexeril (Cyclobenzaprine Hydrochloride)	C				
	Doxepin (Doxepin)	C				
	Remeron (Mirtazapine)	C				
	Trazodone (Trazodone)	C				
	Ambien (Zolpidem Tartrate)	C				
	Zanaflex (Tizanidine Hydrochloride)	C				
	Clonidine (Clonidine)	C				
	Vicodin	C				
	Inderal (Propranolol Hydrochloride)	C				
	Ultram	C				
	Naprosyn (Naproxen)	C				
	Valium (Diazepam)	C				
	Risperdal (Risperidone)	C				
	Depakote (Valproate Semisodium)	C				
	Thiamine (Thiamine)	C				

Mellaril  
(Thioridazine  
Hydrochloride) C  
Imitrex (Sumatriptan  
Succinate) C  
Lithium (Lithium) C  
Seroquel  
(Quetiapine) C  
Cogentin  
(Benzatropin  
Mesilate) C  
Tylenol W/Codeine  
No.3 C  
Albuterol  
(Salbutamol) C  
Klonopin  
(Clonazepam) C  
Atarax (Hydroxyzine  
Hydrochloride) C  
Ativan (Lorazepam) C  
Haldol (Haloperidol) C  
Imitrex "Glaxo"  
(Sumatriptan) C

21-Jul-2006 10:28 AM

Page: 113

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Librium "Hoffman"  
(Chlordiazepoxide  
Hydrochloride) C  
Atenolol (Atenolol) C  
Percocet C  
Prozac (Fluoxetine  
Hydrochloride) C  
Maxalt (Rizatriptan  
Benzoate) C  
Skelaxin  
(Metaxalone) C  
Antivert (Nicotinic  
Acid, Meclozine  
Hydrochloride) C  
Trimox (Amoxicillin  
Trihydrate) C  
Ranitidine  
(Ranitidine) C  
Nexium  
(Esomeprazole) C  
Combivent  
(Ipratropium  
Bromide, Salbutamol  
Sulfate) C  
Tegretol  
(Carbamazepine) C  
Protonix

(Pantoprazole) C

Date:04/20/04ISR Number: 4344955-2Report Type:Expedited (15-DaCompany Report #USA-2002-0002836

Age:45 YR Gender:Male I/FU:F

Outcome PT  
Death Alcohol Withdrawal  
Hospitalization - Syndrome  
Initial or Prolonged Anxiety  
Other Completed Suicide  
Cough  
Cyst  
Depression  
Drug Dependence  
Drug Ineffective  
Drug Withdrawal Syndrome  
Gun Shot Wound  
Hypoaesthesia  
Impaired Driving Ability  
Loss Of Consciousness  
Muscle Spasms  
Oxygen Saturation  
Decreased  
Pain  
Paraesthesia  
Polysubstance Abuse  
Pyrexia  
Rhonchi  
Suicidal Ideation  
Temperature Intolerance  
Upper Respiratory Tract  
Infection  
Weight Decreased

21-Jul-2006 10:28 AM

Page: 114

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Wheezing

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Consumer	Oxycontin Tablets					
Health Professional	20mg (Oxycodone Hydrochloride) Cr					
Other	Tablet PS		ORAL	SEE IMAGE		
	Lorcet (Paracetamol, Hydrocodone Bitartrate)	SS		10 MG		
	Marijuana (Cannabis)	SS		SEE TEXT		
	Remeron (Mirtazapine)	C				
	Ralafen (Nabumetone)	C				
	Neurontin (Gabapentin)	C				



Ultram C  
 Soma (Carisoprodol) C  
 Effexor (Venlafaxine Hydrochloride) C  
 Biaxin (Clarithromycin) C  
 Xanax (Alprazolam) C  
 Zanaflex (Tizanidine Hydrochloride) C  
 Tranxene (Clorazepate Dipotassium) C  
 Zoloft (Sertraline Hydrochloride) C

Date:04/20/04ISR Number: 4345978-XReport Type:Expedited (15-DaCompany Report #FRWYE695207APR04 Age:27 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression Mania	Health Professional	Effexor Lp (Venlafaxine Hydrochloride, Capsule, Extended Release)			ORAL	37.5 MG 2X PER 1 DAY	2 YR
			Cannabis (Cannabis)	SS				
			Zyprexa (Olanzapine)	SS		ORAL	LOW DOSE	

Date:04/23/04ISR Number: 4348612-8Report Type:Expedited (15-DaCompany Report #USA-2003-0011296 Age:23 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Screen Positive Hepatic Steatosis Hypertrophic Cardiomyopathy Obesity Pulmonary Oedema Toxicologic Test Abnormal	Health Professional Other	Oxycodone Hydrochloride (Similar To Nda-20-553) (Oxycodone)	PS				
			Ethanol (Ethanol)	SS				
			Alprazolam (Alprazolam)	SS				
			Cannabis (Cannabis)	SS				

21-Jul-2006 10:28 AM

Page: 115

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:04/28/04ISR Number: 4351177-8Report Type:Periodic Company Report #US-JNJFOC-20030904399 Age:15 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest Drug Abuser	Literature Health	Ultram (Tramadol Hydrochloride)					

Overdose Professional Distributor Tablets Heroin (Diamorphine) PS ORAL ORAL  
 Marijuana (Cannabis) SS INHALATION

Date:05/05/04ISR Number: 4355963-XReport Type:Expedited (15-DaCompany Report #HQWYE575823APR04 Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Amnesia	Consumer	Effexor (Venlafaxine Hydrochloride, Tablet)	PS		ORAL		
	Delusion		Marijuana (Cannabis, )	SS		RESPIRATORY (INHALATION)		
	Homicide					ORAL		
	Mental Disorder							
	Suicidal Ideation							

Date:05/07/04ISR Number: 4356748-0Report Type:Expedited (15-DaCompany Report #KII-2004-0010002 Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cyanosis	Study	Oxycontin Tablets (Oxycodone Hydrochloride) Cr					
Other	Multiple Drug Overdose	Health						
	Polysubstance Abuse	Professional	Tablet	PS		UNKNOWN	UNK, UNK, UNK	
	Respiratory Distress	Other	Alcohol (Ethanol)	SS		UNKNOWN	UNK, UNK, UNK	
			Cocaine (Cocaine)	SS		UNKNOWN	UNK, UNK, UNK	
			Benzodiazepine Derivatives	SS		UNKNOWN	UNK, UNK, UNK	
			Marijuan (Cannabis)	SS		UNKNOWN	UNK, UNK, UNK	
			Acetaminophen (Paracetamol)	SS		UNKNOWN	UNK, UNK, UNK	

Date:05/12/04ISR Number: 4359389-4Report Type:Expedited (15-DaCompany Report #HQWYE661130APR04 Age:19 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Health	Effexor (Venlafaxine Hydrochloride, Tablet)	PS		ORAL	SEE IMAGE	
	Drug Abuser	Professional	Codeine (Codeine,)	SS				
	Drug Interaction	Company	Heroin (Diamorphine,)	SS				
	Drug Toxicity	Representative	Marijuana (Cannabis,)	SS				
			Morphine (Morphine,)	SS				

Date:05/20/04ISR Number: 4366262-4Report Type:Expedited (15-DaCompany Report #USA-2003-0005884 Age:34 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Abnormal Behaviour
Other	Accidental Overdose
	Agitation

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Adverse Event	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Alcohol Withdrawal Syndrome							
Anxiety	Consumer	Oxycontin Tablets					
Arthralgia	Health	(Oxycodone					
Asthma	Professional	Hydrochloride) Cr					
Bipolar I Disorder	Other	Tablet	PS		ORAL	SEE IMAGE	
Blood Glucose Decreased		Xanax (Alprazolam)	SS				
Blood Glucose Increased		Cocaine (Cocaine)	SS				
Blood Prolactin Increased		Marijuana (Cannabis)	SS				
Bronchitis		Neurontin					
Chills		(Gabapentin)	C				
Depressed Level Of Consciousness		Flexeril					
Depression		(Cyclobenzaprine					
Drug Abuser		Hydrochloride)	C				
Drug Dependence		Doxepin (Doxepin)	C				
Drug Ineffective		Remeron					
Drug Withdrawal Syndrome		(Mirtazapine)	C				
Duodenitis		Trazodone					
Dysarthria		(Trazodone)	C				
Dyspepsia		Ambien (Zolpidem					
Dysuria		Tartrate)	C				
Galactorrhoea		Zanaflex (Tizanidine					
Gastritis		Hydrochloride)	C				
Hallucination, Auditory		Clonidine					
Headache		(Clonidine)	C				
Hypertension		Vicodin	C				
Inadequate Analgesia		Inderal (Propranolol					
Insomnia		Hydrochloride)	C				
Lymphadenopathy		Ultram	C				
Mental Disorder		Naprosyn (Naproxen)	C				
Migraine		Valium (Diazepam)	C				
Mydriasis		Risperdal					
Neck Pain		(Risperidone)	C				
Night Sweats		Depakote (Valproate					
Overdose		Semisodium)	C				
Pain		Thiamine (Thiamine)	C				
Paraesthesia Oral		Mellaril					
Psychomotor Hyperactivity		(Thioridazine					
Pulmonary Congestion		Hydrochloride)	C				
Respiratory Rate Decreased		Imitrex (Sumatriptan					
Sedation		Succinate)	C				
Sinusitis		Lithium (Lithium)	C				
Thirst		Seroquel Quetiapine)	C				
Vision Blurred		Cogentin					
		(Benzatropine					
		Mesilate)	C				
		Tylenol W/Codeine					
		No. 3	C				
		Albuterol					
		(Salbutamol)	C				
		Klonopin					

(Clonazepam) C  
 Atarax (Hydroxyzine Hydrochloride) C  
 Ativan (Lorazepam) C  
 Haldol (Haloperidol) C  
 Imitrex "Glaxo"  
 (Sumatriptan) C Glaxo  
 Librium "Hoffman"  
 (Chlordiazepoxide)

21-Jul-2006 10:28 AM

Page: 117

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Hydrochloride) C  
 Atenolol (Atenolol) C  
 Percocet C  
 Prozac (Fluoxetine Hydrochloride) C  
 Maxalt (Rizatriptan Benzoate) C  
 Skelaxin  
 (Metaxalone) C  
 Antivert (Icotinic Acid, Meclozie Hydrochloride) C  
 Trimox (Amoxicillin Trihydrate) C  
 Ranitidine  
 (Ranitidine) C  
 Nexium  
 (Esomeprazole) C  
 Combivent  
 (Ipratropium Bromide, Salbutamol, Sulfate) C  
 Tegretol  
 (Carbamazepine) C  
 Protonix  
 (Pantoprazole) C

Date:05/26/04ISR Number: 4367202-4Report Type:Expedited (15-DaCompany Report #2012272

Age:42 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Consumer	Oxycontin Tablets					
Hospitalization - Initial or Prolonged	Asthenia Back Pain	Health Professional	(Oxycodone Hydrochloride) Cr					
Other	Drug Abuser	Other	Tablet	PS		SEE IMAGE		
Required Intervention to Prevent Permanent Impairment/Damage	Drug Level Below Therapeutic Drug Toxicity Erectile Dysfunction		Diazepam (Diazepam) Oxazepam (Oxazepam) Temazepam (Temazepam)	SS SS SS				
	Haematuria Headache		Lorazepam (Lorazepam)	SS				

Iron Deficiency Anaemia	Cannabnoids	
Mallory-Weiss Syndrome	(Cannabis)	SS
Neck Pain	Diphenhydramine	
Respiratory Arrest	Hydrochloride	
Tachycardia	(Diphenhydramine	
Upper Gastrointestinal	Hydrochloride)	SS
Haemorrhage	Gabapentin	
	(Gabapentin)	SS
	Claritin	
	(Loratadine)	C
	Zoloft (Sertraline	
	Hydrochloride)	C
	Altace (Ramipril)	C
	Allopurinol	
	(Allopurinol)	C
	Depakote (Valproate	
	Semisodium)	C
	Soma (Carisoprodol)	C
	Relafen (Nabumetone)	C

21-Jul-2006 10:28 AM

Page: 118

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/27/04ISR Number: 4369412-9Report Type:Expedited (15-DaCompany Report #KII-2004-0010500 Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression Agitation	Study Health	Oxycontin Tablets (Oxycodone					
	Alcohol Withdrawal Syndrome	Professional Other	Hydrochloride) Cr Tablet PS			ORAL	ORAL	
	Confusional State		Cyclobenzaprine					
	Drug Screen Positive		(Cyclobenzaprine)	SS		ORAL	ORAL	
	False Positive Laboratory Result		Phenothiazine					
	Hallucination		(Phenothiazine)	SS				
	Heart Rate Increased		Marijuana (Cannabis)	SS				
	Mydriasis							
	Pyrexia							
	Restlessness							

Date:06/03/04ISR Number: 4372852-5Report Type:Expedited (15-DaCompany Report #USA-2003-0009433 Age:42 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Back Pain Delusion	Consumer Health	Oxycontin Tablets (Oxycodone					
Other	Disturbance In Attention	Professional	Hydrochloride)Cr					
	Drug Abuser	Other	Tablet PS			ORAL	20 MG, BID,	
	Drug Dependence					ORAL		
	Drug Ineffective		Alcohol (Ethanol)	SS				
	Drug Withdrawal Syndrome		Marijuana (Cannabis)	SS				
	Feeling Abnormal		Cocaine (Cocaine)	C				

Hallucination, Auditory  
 Insomnia  
 Major Depression  
 Memory Impairment  
 Pain  
 Psychotic Disorder  
 Schizophrenia, Paranoid  
 Type  
 Weight Fluctuation

Norco C  
 Xanax (Alprazolam) C

Date:06/10/04ISR Number: 4379337-0Report Type:Expedited (15-DaCompany Report #KII-2004-0010993

Age:19 YR Gender:Female I/FU:I

Outcome PT  
 Hospitalization - Anxiety  
 Initial or Prolonged Blood Glucose Increased  
 Other Body Temperature  
 Increased  
 Diarrhoea  
 Drug Abuser  
 Gait Disturbance  
 Hyperventilation  
 Metabolic Acidosis  
 Nausea  
 Polysubstance Abuse  
 Refusal Of Treatment By  
 Patient  
 Respiratory Alkalosis  
 Tremor  
 Urine Ketone Body Present

21-Jul-2006 10:28 AM

Page: 119

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Vomiting  
 White Blood Cell Count  
 Increased

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Study Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-553) (Oxycodone Hydrochloride)	PS		ORAL	ORAL	
	Marijuana (Cannabis)	SS		RESPIRATORY (INHALATION)	INHALATION	
	Mushroom()	SS		ORAL	ORAL	
	Tramadol (Tramadol)	C				
	Oral Contraceptive Nos (Oral Contraceptive Nos)	C				

Date:06/10/04ISR Number: 4379405-3Report Type:Expedited (15-DaCompany Report #KII-2003-0011064

Age:18 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Acute Respiratory Failure	Study	Morphine Sulfate					
Other	Blood Ph Decreased	Other	(Similar To Nda					
	Lethargy		19-516 (Morphine Sulfate)	PS				
	Pco2 Increased		Methadone					
	Pneumonia		(Methadone)	SS				
	Polysubstance Abuse		Marijuana (Cannabis)	SS				
	Somnolence		Amfetamine					
	Vomiting		(Amfetamine)	SS				
			Benzodiazepine Derivatives	SS				

Date:06/15/04ISR Number: 4381680-6Report Type:Expedited (15-DaCompany Report #KII-2004-0011112

Age:52 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Abnormal Behaviour
Other	Aggression
	Agitation
	Anger
	Aspartate
	Aminotransferase
	Increased
	Back Pain
	Blood Alkaline
	Phosphatase Increased
	Blood Glucose Increased
	Blood Pressure Systolic
	Increased
	Blood Urea Increased
	Body Temperature
	Decreased
	Convulsion
	Delirium
	Disorientation
	Drug Abuser
	Drug Withdrawal Syndrome
	Grunting
	Hyperhidrosis

21-Jul-2006 10:28 AM

Page: 120

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Loss Of Consciousness

Moaning

Overdose

Patient Restraint

Pupillary Reflex Impaired

Somnolence

Stupor

Tremor

Report Source

Study

Health

Professional

Other

Product

Oxycontin

Tablets(Oxycodone

Hydrochloride) Cr

Tablet

Benzodiazepine

Role

PS

Manufacturer

ORAL

Route

ORAL

Dose

Duration

Urinary Incontinence	Derivatives ( )	SS	ORAL	ORAL
White Blood Cell Count Increased	Baclofen (Baclofen)	SS	ORAL	ORAL
White Blood Cells Urine Positive	Docusate Sodium (Docusate Sodium)	SS		ORAL
	Marijuana (Cannabis)	SS		
	Tricyclic Antidepressants( )	SS		
	Ultram (Tramadol Hydrochloride)	SS		
	Antiepileptics ( )	SS		

Date:06/16/04ISR Number: 4381197-9Report Type:Expedited (15-DaCompany Report #2012272 Age:42 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accident	Consumer	Oxycontin Tablets					
Hospitalization - Initial or Prolonged	Accidental Overdose	Health Professional	(Oxycodone Hydrochloride)Cr					
Other	Back Pain	Other	Tablet	PS		SEE IMAGE		
Required	Drug Abuser		Diazepam (Diazepam)	SS				
Intervention to Prevent Permanent Impairment/Damage	Erectile Dysfunction		Oxazepam (Oxazepam)	SS				
	Haematemesis		Temazepam (Temazepam)	SS				
	Haemorrhage							
	Headache		Lorazepam (Lorazepam)	SS				
	Iron Deficiency Anaemia							
	Mallory-Weiss Syndrome		Cannabnoids (Cannabis)	SS				
	Respiratory Arrest							
	Tachycardia		Diphenhydramine Hydrochloride (Diphenhydramine Hydrochloride)	SS				
	Tooth Disorder							
	Tooth Extraction							
			Gabapentin (Gabapentin)	SS				
			Claritin (Loratadine)	C				
			Zoloft (Sertraline Hydrochloride)	C				
			Altace (Ramipril)	C				
			Allopurinol (Allopurinol)	C				
			Depakote (Valproate Semisodium)	C				
			Soma (Carisoprodol)	C				
			Relafen (Nabumetone)	C				

Date:06/18/04ISR Number: 4384256-XReport Type:Expedited (15-DaCompany Report #DEWYE821914JUN04 Age:24 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Abuser	Health Professional	Trevilor (Venlafaxine)					
	Memory Impairment							



Freedom Of Information (FOI) Report

Hydrochloride, Tablet)	PS	ORAL	75 MG 10X PER 1 DAY ORAL 1 DAY
Aponal (Doxepin Hydrochloride)	SS	ORAL	100 MG 10X PER 1 DAY ORAL 1 DAY
Bespar (Buspirone Hydrochloride)	SS	ORAL	ORAL 1 DAY
Cannabis (Cannabis)	SS	(INHALATION)	RESPIRATORY INHALATION 1 DAY
Diazepam	SS	ORAL	3-6 TABLETS ORAL 1 DAY

Date:06/21/04ISR Number: 4384807-5Report Type:Expedited (15-DaCompany Report #DEWYE821914JUN04

Age:24 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Intentional Overdose Memory Impairment	Health Professional	Trevilor (Venlafaxine Hydrochloride, Tablet, 0)	PS		ORAL	75 MG 10X PER 1 DAY ORAL 1 DAY	
			Aponal (Doxepin Hydrochloride, , 0)	SS		ORAL	100 MG 10X PER 1 DAY ORAL 1 DAY	
			Bespar (Buspirone Hydrochloride, ,0) Cannabis (Cannabis, , 0)	SS SS		ORAL	ORAL 1 DAY RESPIRATORY (INHALATION) INHALATION 1 DAY	
			Diazepam (Diazepam, , 0)	SS		ORAL	3-6 TABLETS ORAL 1 DAY	

Date:06/21/04ISR Number: 4391096-4Report Type:Periodic Company Report #USA-2003-0009448

Age:19 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose Cardiac Arrest	Consumer Health Professional Company Representative Other	Oxycontin Tablets (Oxycodone Hydrochloride) Benzodiazepine Derivatives Cannabis (Cannabis)	PS SS SS		UNK UNK UNK		

Date:06/21/04ISR Number: 4391104-0Report Type:Periodic Company Report #USA-2003-0009554

Age:39 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose Multiple Drug Overdose	Consumer Health	Oxycontin Tablets (Oxycodone					

Professional	Hydrochloride)	PS	UNK
Other	Hydrocodone		
	Bitartrate (Similar		
	To Ind 59,175)		
	(Hydro (Cont)	SS	UNK
	Hydromorphone Hcl		

21-Jul-2006 10:28 AM

Page: 122

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

(Similar To Ind			
38,424) (Hydromorph	SS		UNK
Alprazolam			
(Alprazolm)	SS		
Cannabis (Cannabis)	SS		UNK
Acetaminophen			
(Paracetamol)	SS		UNK
Nicotine (Nicotine)	SS		UNK

Date:06/21/04ISR Number: 4391132-5Report Type:Periodic Company Report #USA-2003-0011589 Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda					
			20-553) (Oxycodone					
			Hydrochloride)	PS		UNK MG		
			Hydrocodone					
			Bitartrate (Similar					
			To Ind 59,175)					
			(Hydrocodone					
			Bitartrate)	SS		UNK MG		
			Acetaminophen					
			(Paracetamol)	SS				
			Cannabis (Cannabis)	SS				
			Ibuprofen					
			(Ibuprofen)	SS				

Date:06/21/04ISR Number: 4391137-4Report Type:Periodic Company Report #USA-2003-0011595 Age:31 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycontin Tablets					
	Multiple Drug Overdose	Professional	(Oxycodone					
	Other		Hydrochloride)	PS		UNK MG		
			Morphine Sulfate					
			(Similar To Nda					
			19-516) (Morphine					
			Sulfate)	SS		UNK MG		
			Cocaine (Cocaine)	SS		UNK MG		
			Carisoprodol					
			(Carisoprodol)	SS				

Cannabis (Cannabis) SS  
Nicotine (Nicotine) SS

Date:06/21/04ISR Number: 4391139-8Report Type:Periodic Company Report #USA-2003-0011599 Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda					
			20-553) (Oxycodone					
			Hydrochloride) PS			UNK MG		
			Hydrocodone					
			Bitartrate (Similar					
			To Ind 59,175)					
			(Hydrocodone					

21-Jul-2006 10:28 AM

Page: 123

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Bitartrate)	SS	UNK MG
Acetaminophen		
(Paracetamol)	SS	
Caffeine (Caffeine)	SS	
Diphenhydramine		
(Diphenhydramine)	SS	
Nicotine (Nicotine)	SS	
Cannabis (Cannabis)	SS	
Alprazolam		
(Alprazolam)	SS	
Mirtazapine		
(Mirtazapine)	SS	

Date:06/21/04ISR Number: 4391147-7Report Type:Periodic Company Report #USA-2003-0009899 Age:28 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Consumer	Oxycontin Tablets					
	Multiple Drug Overdose	Health	(Oxycodone					
		Professional	Hydrochloride)	PS				
		Other	Benadryl					
			(Diphenhydramine					
			Hydrochloride)	SS				
			Methadone					
			(Methadone)	SS				
			Alcohol (Ethanol)	SS				
			Marijuana (Cannabis)	SS				
			Pseudoephedrine					
			(Pseudoephedrine)	SS				
			Diazepam (Diazepam)	SS				
			Ephedrine					
			(Ephedrine)	SS				

Date:06/21/04ISR Number: 4391161-1Report Type:Periodic Company Report #USA-2003-0011571 Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose Multiple Drug Overdose Other	Health Professional	Oxycodone Hydrochloride (Similar To Nda 20-553) (Oxycodone Hydrochloride) PS Hydrocodone Bitartrate (Similar To Ind 59, 175) (Hydrocodone Bitartrate) SS Ethanol (Ethanol) SS Cocaine (Cocaine) SS Alprazolam (Alprazolam) SS Cannabis (Cannabis) SS Acetaminophen (Paracetamol) SS					
						L MG		

21-Jul-2006 10:28 AM

Page: 124

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/21/04ISR Number: 4391177-5Report Type:Periodic Company Report #USA-2003-0011582 Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose Multiple Drug Overdose Other	Health Professional	Oxycodone Hydrochloride (Similar To Nda 20-553) (Oxycodone Hydrochloride) PS Cocaine (Cocaine) SS Diazepam (Diazepam) SS Oxazepam (Oxazepam) SS Cannabis (Cannabis) SS Lidocaine (Lidocaine) SS Atenolol (Atenolol) SS					
						MG MG MG MG		
						MG MG		

Date:06/21/04ISR Number: 4391206-9Report Type:Periodic Company Report #USA-2002-0000617 Age:26 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Agitation	Consumer	Oxycontin Tablets 10					



Date:06/21/04ISR Number: 4391236-7Report Type:Periodic Company Report #USA-2003-0005841 Age:25 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Abuser	Consumer	Oxycontin Tablets					
Other	Drug Dependence	Health	(Oxycodone					
	Loss Of Consciousness	Professional	Hydrochloride)	PS				
	Multiple Drug Overdose	Other	Morphine Sulfate					
	Accidental		(Similar To Nda					
			19-516) (Morphine					
			Sulfate) SS					
			Cocaine (Cocaine) SS					
			Diazepam (Diazepam) SS					
			Xanax (Alprazolam) SS					
			Marijuana (Cannabis) SS					
			Lidocaine					
			(Lidocaine) SS					
			Caffeine (Caffeine) SS					
			Temazepam					
			(Temazepam) SS					
			Codeine (Codeine) SS					

Date:06/21/04ISR Number: 4395292-1Report Type:Periodic Company Report #USA-2003-0010430 Age:26 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Health	Oxycontin Tablets					
	Parosmia	Professional	(Oxycodone					
			Hydrochloride) PS			80 MG, BID		
			Marijuana (Cannabis) SS					
			Xanax C					

Date:06/21/04ISR Number: 4395301-XReport Type:Periodic Company Report #USA-2003-0010455 Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Consumer	Oxycontin Tablets					
	Drug Abuser	Health	(Oxycodone					
	Multiple Drug Overdose	Professional	Hydrochloride)	PS				
	Other		Hydrocodone					
			Bitartrate (Similar					
			To Ind 59,175)					
			(Hydrocodone					
			Bitartrate, SS					
			Alcohol (Ethanol) SS			UNK L		
			Cannabis (Cannabis) SS					
			Propoxyphene					

) SS

Date:06/21/04ISR Number: 4396007-3Report Type:Periodic Company Report #USA-2003-0010870 Age:22 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose Multiple Drug Overdose Other	Health Professional	Oxycodone Hydrochloride (Similar To Nda 20-553) (Oxycodone Hydrochloride)	PS	UNKNOWN	UNK UNK, UNK;		
			Cocaine (Cocaine)	SS	UNKNOWN	UNK UNK, UNK;		
			Cannabis (Cannabis)	SS	UNKNOWN	UNK UNK, UNK;		

Date:06/21/04ISR Number: 4396048-6Report Type:Periodic Company Report #USA-2003-0010839 Age:22 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose Multiple Drug Overdose Other	Health Professional	Oxycodone Hydrochloride (Similar To Nda 20-553) (Oxycodone Hydrochloride)	PS				
			Cocaine (Cocaine)	SS				
			Alprazolam (Alprazolam)	SS				
			Metamphetamine (Metamphetamine)	SS				
			Amphetamine (Amphetamine)	SS				
			Cannabis (Cannabis)	SS				
			Phenylpropanolamine (Phenylpropanolamine )	SS				
			Ephedrine (Ephedrine)	SS				
			Pseudoephedrine (Pseudoephedrine)	SS				
			Depakote	C				
			Risperdal	C				
			Paxil	C				
			Buspar	C				

Date:06/21/04ISR Number: 4396054-1Report Type:Periodic Company Report #USA-2003-0011070 Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health Professional Other	Oxycodone Hydrochloride Cannabis (Cannabis) Caffeine (Caffeine)	PS SS SS				





Date:06/21/04ISR Number: 4396103-0Report Type:Periodic Company Report #USA-2003-0011033 Age:15 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycontin Tablets					
		Professional	(Oxycodone					
		Other	Hydrochloride)	PS			MG	
			Nicotine (Nicotine)	SS			MG	
			Citalopram					
			(Citalopram)	SS			MG	
			Cannabinoids	SS			MG	

21-Jul-2006 10:28 AM

Page: 128

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/21/04ISR Number: 4396106-6Report Type:Periodic Company Report #USA-2003-0011034 Age:16 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycontin Tablets					
		Professional	(Oxycodone					
		Other	Hydrochloride)	PS				
			Clonazepam					
			(Clonazepam)	SS				
			Propoxyphene					
			(Dextropropoxyphene)	SS				
			Cannabis (Cannabis)	SS				
			Nicotine (Nicotine)	SS				
			Caffeine (Caffeine)	SS				

Date:06/21/04ISR Number: 4396117-0Report Type:Periodic Company Report #USA-2003-0011036 Age:26 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycontin Tablets					
		Professional	(Oxycodone					
		Other	Hydrochloride)	PS			80 MG	
			Nicotine (Nicotine)	SS				
			Remeron					
			(Mirtazapine)	SS	ORAL		1 TABELT, HS,	
					ORAL			
			Cannabis (Cannabis)	SS				
			Clonazepam					
			(Clonazepam)	SS	ORAL		TID, ORAL	

Date:06/21/04ISR Number: 4396152-2Report Type:Periodic Company Report #USA-2003-0011026 Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					

Multiple Drug Overdose  
 Other  
 Professional  
 Hydrochloride  
 (Similar To Nda  
 20-553) (Oxycodone  
 Hydrochloride) PS  
 Hydrocodone  
 Bitartrate (Similar  
 To Ind 59,175)  
 (Hydrocodone  
 Bitartrate) SS  
 Fentanyl (Fentanyl) SS  
 Elavil  
 (Amitriptyline  
 Hydrochloride) SS  
 Alprazolam  
 (Alprazolam) SS  
 Ethanol (Ethanol) SS  
 Caffeine (Caffeine) SS  
 Cannabis (Cannabis) SS  
 Nicotine (Nicotine) SS  
 Voltaren C  
 Trilafon C  
 Flexeril C  
 Vicodin Es C

21-Jul-2006 10:28 AM

Page: 129

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/21/04ISR Number: 4396458-7Report Type:Periodic Company Report #USA-2002-0002869 Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Other	Accidental Overdose Drug Abuser Other	Health Professional	Oxycontin Tablets (Oxycodone Hydrochloride)	PS		ORAL	ORAL	
			Alprazolam (Alprazolam)	SS				
			Temazepam (Temazepam)	SS				
			Canabanoids (Cannabis)	SS				
			Diazepam (Diazepam)	SS				
			Nicotine (Nicotine)	SS				
			Caffeine (Caffeine)	SS				
			Acetaminophen (Paracetamol)	SS				

Date:06/21/04ISR Number: 4396528-3Report Type:Periodic Company Report #USA-2003-0010337 Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose Multiple Drug Overdose	Consumer Health	Oxycontin Tablets (Oxycodone					

Professional Hydrochloride) PS  
 Other Alcohol (Ethanol) SS  
 Marijuana (Cannabis) SS

Date:06/21/04ISR Number: 4396540-4Report Type:Periodic Company Report #USA-2003-0010310 Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
		Professional	Hydrochloride					
		Other	(Similar To Nda					
			20-553) (Oxycodone					
			Hydrochloride) PS					
			Salicylic Acid					
			(Salicylic Acid) SS					
			Cannabis (Cannabis) SS					
			Caffeine (Caffeine) SS					
			Nicotine (Nicotine) SS					

Date:06/21/04ISR Number: 4396548-9Report Type:Periodic Company Report #USA-2003-0009143 Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Consumer	(Oxycodone					
Other	Delusion	Health	Hydrochloride					
	Depression	Professional	(Similar To Nda					
	Drug Abuser	Other	20-553) (Oxycodone					
	Euphoric Mood		Hydrochloride) PS					
	Mood Swings		Morphine Sulfate					
	Multiple Drug Overdose		(Similar To Nda					
			19-516) SS					
			Diazepam SS					
			Temazepam SS					
			Cannabis SS					

21-Jul-2006 10:28 AM

Page: 130

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Caffeine SS  
 Nicotine SS

Date:06/21/04ISR Number: 4396853-6Report Type:Periodic Company Report #USA-2004-0013863 Age:26 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Polysubstance Abuse	Consumer	Oxycontin Tablets					
		Other	(Oxycodone					
			Hydrochloride) PS			MG		
			Marijuana (Cannabis) SS					
			Ecstasy					
			(Methylendioxyamphet					

amine) SS  
 Cocaine (Cocaine) SS  
 Flexeril  
 (Cyclobenzaprine  
 Hydrochloride) SS

Date:06/21/04ISR Number: 4396913-XReport Type:Periodic Company Report #USA-2004-0014203 Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Polysubstance Abuse Other	Consumer	Oxycontin Tablets (Oxycodone Hydrochloride)	PS				
			Cocaine (Cocaine)	SS				
			Methadone (Methadone)	SS				
			Marijuana (Cannabis)	SS				

Date:06/21/04ISR Number: 4396940-2Report Type:Periodic Company Report #USA-2004-0013669 Age:34 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser Other	Consumer	Oxycontin Tablets (Oxycodone Hydrochloride)	PS	UNKNOWN	UNK MG, UNK;		
			Xanax (Alprazolam)	SS	UNKNOWN	UNK UNK, UNK;		
			Cocaine (Cocaine)	SS	UNKNOWN	UNK UNK, UNK;		
			Heroin (Diamorphine)	SS	UNKNOWN	UNK UNK, UNK;		
			Marijuana (Cannabis)	SS	UNKNOWN	UNK UNK, UNK;		

Date:06/21/04ISR Number: 4396968-2Report Type:Periodic Company Report #USA-2003-0012371 Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Other	Accidental Overdose Drug Abuser Drug Dependence Multiple Drug Overdose	Consumer Health Professional Other	Oxycontin Tablets (Oxycodone Hydrochloride)	PS		UNKNOWN UNKNOWN	UNK UNK, UNK;	
		Roxicet						

21-Jul-2006 10:28 AM

Page: 131

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

(Paracetamol,  
 Oxycodone  
 Hydrochloride) SS  
 UNKNOWN  
 UNKNOWN  
 5 MG DAILY;

Alprazolam (Alprazolam)	SS	UNKNOWN UNKNOWN	UNK UNK, UNK;
Acetaminophen (Paracetamol)	SS	UNKNOWN UNKNOWN	UNK UNK, UNK;
Marijuana (Cannabis)	SS	UNKNOWN UNNOWN	UNK UNK, UNK;

Date:06/21/04ISR Number: 4396980-3Report Type:Periodic Company Report #USA-2003-0012260 Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Consumer	Oxycontin Tablets					
Other	Drug Abuser	Health Professional Other	(Oxycodone Hydrochloride)	PS	UNKNOWN UNKNOWN		UNK MG, UNK;	
			Metamfetamine (Metamfetamine)	SS	UNKNOWN UNKNOWN		UNK UNK, UNK;	
			Acetaminophen (Paracetamol)	SS	UNKNOWN UNKNOWN		UNK UNK, UNK;	
			Marijuana (Cannabis)	SS	UNKNOWN UNKNOWN		UNK UNK, UNK;	
			Ethanol (Ethanol)	SS	UNKNOWN UNKNOWN		UNK UNK, UNK;	
			Benzodiazepine Derivatives	SS	UNKNOWN UNKNOWN		UNK UNK, UNK;	

Date:06/21/04ISR Number: 4397023-8Report Type:Periodic Company Report #USA-2004-0013582 Age:26 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Polysubstance Abuse Other	Consumer	Oxycontin Tablets					
			(Oxycodone Hydrochloride)	PS				
			Cocaine (Cocaine)	SS				
			Heroin (Heroin)	SS				
			Marijuana (Marijuana)	SS				

Date:06/21/04ISR Number: 4397089-5Report Type:Periodic Company Report #USA-2004-0014168 Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Impaired Driving Ability Polysubstance Abuse Road Traffic Accident	Consumer Other	Oxycodone Hydrochloride (Similar To Nda 20-553) (Oxycodone Hydrochloride)	PS				
			Marijuana (Cannabis)	SS				

## FDA - Adverse Event Reporting System (AERS)

## Freedom Of Information (FOI) Report

Date:06/21/04ISR Number: 4397171-2Report Type:Periodic Company Report #USA-2004-0013313 Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Polysubstance Abuse Other	Consumer	Oxycontin (Oxycodone Hydrochloride) PS Cocaine (Cocaine) SS Marijuana (Cannabis) SS					

Date:06/21/04ISR Number: 4397172-4Report Type:Periodic Company Report #USA-2004-0013314 Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Polysubstance Abuse Other	Consumer	Oxycontin Tablets (Oxycodone Hydrochloride) PS Cocaine (Cocaine) SS Marijuana (Cannabis) SS D					

Date:06/21/04ISR Number: 4397208-0Report Type:Periodic Company Report #USA-2004-0012956 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser Other	Consumer	Oxycontin Tablets (Oxycodone Hydrochloride) PS Marijuana (Cannabis) SS Cocaine (Cocaine) SS Methylenedioxyamphet amine (Methylenedioxyamphe tamine) SS			MG		

Date:06/21/04ISR Number: 4397212-2Report Type:Periodic Company Report #USA-2004-0012957 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser Other	Consumer	Oxycontin Tablets (Oxycodone Hydrochloride) PS Marijuana (Cannabis) SS Cocaine (Cocaine) SS Methylenedioxyamphet amine (Methylenedioxyamphe tamine) SS			MG		

Date:06/21/04ISR Number: 4397214-6Report Type:Periodic Company Report #USA-2004-0012958 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride)	PS		MG		
			Marijuana (Cannabis)	SS				
			Cocaine (Cocaine)	SS				

21-Jul-2006 10:28 AM

Page: 133

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Methylenedioxyamphet  
amine  
(Methylenedioxyamphe  
tamine) SS

Date:06/21/04ISR Number: 4397216-XReport Type:Periodic Company Report #USA-2004-0012959 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride)	PS		MG		
			Marijuana (Cannabis)	SS				
			Cocaine (Cocaine)	SS				
			Methylenedioxyamphet amine (Methylenedioxyamphe tamine)	SS				

Date:06/21/04ISR Number: 4397217-1Report Type:Periodic Company Report #USA-2004-0012960 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride)	PS		MG		
			Marijuana (Cannabis)	SS				
			Cocaine (Cocaine)	SS				
			Methylenedioxyamphet amine (Methylenedioxyamphe tamine)	SS				

Date:06/21/04ISR Number: 4397219-5Report Type:Periodic Company Report #USA-2004-0012961 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride)	PS		MG		
			Marijuana (Cannabis)	SS				
			Cocaine (Cocaine)	SS				
			Methylenedioxyamphetamine (Methylenedioxyamphetamine)	SS				

Date:06/21/04ISR Number: 4397221-3Report Type:Periodic Company Report #USA-2004-0012962 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride)	PS		MG		
			Marijuana (Cannabis)	SS				
			Cocaine (Cocaine)	SS				

21-Jul-2006 10:28 AM

Page: 134

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Methylenedioxyamphetamine (Methylenedioxyamphetamine)

Date:06/21/04ISR Number: 4397225-0Report Type:Periodic Company Report #USA-2004-0012963 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride)	PS		MG		
			Marijuana (Cannabis)	SS				
			Cocaine (Cocaine)	SS				
			Methylenedioxyamphetamine (Methylenedioxyamphetamine)	SS				

Date:06/21/04ISR Number: 4397228-6Report Type:Periodic Company Report #USA-2004-0012964 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride)	PS		MG		



Marijuana (Cannabis) SS  
Cocaine (Cocaine) SS  
Methylenedioxyamphet  
amine  
(Methylenedioxyamphe  
tamine) SS

Date:06/21/04ISR Number: 4397231-6Report Type:Periodic Company Report #USA-2004-0012965 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride) PS			MG		
			Marijuana (Cannabis) SS					
			Cocaine (Cocaine) SS					
			Methylenedioxyamphet amine (Methylenedioxyamphe tamine) SS					

Date:06/21/04ISR Number: 4397234-1Report Type:Periodic Company Report #USA-2004-0013441 Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Dependence	Consumer	Oxycontin Tablets					
	Polysubstance Abuse	Other	(Oxycodone Hydrochloride) PS					
			Marijuana (Cannabis) SS					

21-Jul-2006 10:28 AM

Page: 135

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/21/04ISR Number: 4397241-9Report Type:Periodic Company Report #USA-2004-0013468 Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride) PS			MG,		
			Marijuana (Cannabis) SS					
			Opiods SS					

Date:06/21/04ISR Number: 4397242-0Report Type:Periodic Company Report #USA-2004-0013309 Age:44 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone Hydrochloride					
	Multiple Drug Overdose	Professional	(Similar To Nda					
		Other						

20-553) (Oxycodone  
 Hydrochloride) PS  
 Hydrocodone  
 Bitartrate (Similar  
 To Ind 59,175)  
 (Hydrocodone  
 Bitartrate) SS  
 Alprazolam  
 (Alprazolam) SS  
 Marijuana (Cannabis) SS  
 Acetaminophen  
 (Paracetamol) SS  
 Caffeine (Caffeine) SS

Date:06/21/04ISR Number: 4397342-5Report Type:Periodic Company Report #USA-2004-0013318 Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
	Multiple Drug Overdose	Professional	Hydrochloride					
	Other	(Similar To Nda	20-553) (Oxycodone					
		Hydrochloride)	PS					
		Mepivacaine						
		(Mepivacaine)	SS					
		Morphine Sulfate						
		(Similar To Nda						
		19-516) (Morphine						
		Sulfate)	SS					
		Methadone						
		(Methadone)	SS					
		Acetaminophen						
		(Paracetamol)	SS					
		Marijuana (Cannabis)	SS					
		Cocaine (Cocaine)	SS					
		Nicotine (Nicotine)	SS					
		Caffeine (Caffeine)	SS					
		Alprazolam						
		(Alprazolam)	SS					
		Benzodiazepine						
		Derivatives	SS					
		Hydroxyzine	C					
		Chlorpromazine	C					

21-Jul-2006 10:28 AM

Page: 136

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/21/04ISR Number: 4397351-6Report Type:Periodic Company Report #USA-2004-0013519 Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Consumer	Oxycontin Tablets					
Other	Multiple Drug Overdose	Health	(Oxycodone					
	Polysubstance Abuse	Professional	Hydrochloride)	PS				

Other Hydrocodone Bitartrate (Similar To Ind 59,175) (Hydrocodone Bitartrate) SS  
 Xanax (Alprazolam) SS  
 Marijuana (Cannabis) SS  
 Cocaine (Cocaine) SS  
 Heroin (Diamorphine) SS  
 Antihistamines For Systemic Use SS  
 Amfetamine (Amfetamine) SS  
 Phenylpropanolamine (Phenylpropanolamine ) SS

Date:06/21/04ISR Number: 4397376-0Report Type:Periodic Company Report #USA-2003-0011812 Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Multiple Drug Overdose Accidental	Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-553) (Oxycodone Hydrochloride) PS Alprazolam (Alprazolam) SS Ethanol (Ethanol) SS Cannabis (Cannabis) SS					

Date:06/21/04ISR Number: 4397426-1Report Type:Periodic Company Report #USA-2004-0012873 Age:22 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer Other	Oxycontin Tablets (Oxycodone Hydrochloride) PS Marijuana (Cannabis) SS Cocaine (Cocaine) SS					

Date:06/21/04ISR Number: 4397438-8Report Type:Periodic Company Report #USA-2004-0012921 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer Other	Oxycontin Tablets (Oxycodone Hydrochloride) PS Marijuana (Cannabis) SS Cocaine (Cocaine) SS Methylenedioxyamphet amine			MG		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

(Methylenedioxypheta  
mine) SS

Date:06/21/04ISR Number: 4397439-XReport Type:Periodic Company Report #USA-2004-0012922 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride)	PS		MG		
			Marijuana (Cannabis)	SS				
			Cocaine (Cocaine)	SS				
			Methylenedioxyamphet amine (Methylenedioxyamphe tamine)	SS				

Date:06/21/04ISR Number: 4397441-8Report Type:Periodic Company Report #USA-2004-0012923 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride)	PS		MG		
			Marijuana (Cannabis)	SS				
			Cocaine (Cocaine)	SS				
			Methylenedioxyamphet amine (Methylenedioxyamphe tamine)	SS				

Date:06/21/04ISR Number: 4397443-1Report Type:Periodic Company Report #USA-2004-0012924 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride)	PS		MG		
			Marijuana (Cannabis)	SS				
			Cocaine (Cocaine)	SS				
			Methylenedioxyamphet amine (Methylenedioxyamphe tamine)	SS				

Date:06/21/04ISR Number: 4397445-5Report Type:Periodic Company Report #USA-2004-0012925 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					

Other (Oxycodone Hydrochloride) PS MG  
 Marijuana (Cannabis) SS  
 Cocaine (Cocaine) SS  
 Methylenedioxyamphet  
 amine  
 (Methylenedioxyampe  
 tamine) SS

21-Jul-2006 10:28 AM

Page: 138

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/21/04ISR Number: 4397448-0Report Type:Periodic Company Report #USA-2004-0012926 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride) PS Marijuana (Cannabis) SS Cocaine (Cocaine) SS Methylenedioxyamphet amine (Methylenedioxyampe tamine) SS					

Date:06/21/04ISR Number: 4397449-2Report Type:Periodic Company Report #USA-2004-0012927 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride) PS Marijuana (Cannabis) SS Cocaine (Cocaine) SS Methylenedioxyamphet amine (Methylenedioxyampe tamine) SS					

Date:06/21/04ISR Number: 4397451-0Report Type:Periodic Company Report #USA-2004-0012928 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride) PS Marijuana (Cannabis) SS Cocaine (Cocaine) SS Methylenedioxyamphet amine (Methylenedioxyampe tamine) SS					

Date:06/21/04ISR Number: 4397452-2Report Type:Periodic Company Report #USA-2004-0012929 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride)	PS				
			Marijuana (Cannabis)	SS				
			Cocaine (Cocaine)	SS				
			Methylenedioxyamphet amine					
			(Methylenedioxyamphe tamine)	SS				

21-Jul-2006 10:28 AM

Page: 139

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/21/04ISR Number: 4397455-8Report Type:Periodic Company Report #USA-2004-0012930 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride)	PS				
			Marijuana (Cannabis)	SS				
			Cocaine (Cocaine)	SS				
			Methylenedioxyamphet amine					
			(Methylenedioxyamphe tamine)	SS				

Date:06/21/04ISR Number: 4397457-1Report Type:Periodic Company Report #USA-2004-0012931 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride)	PS				
			Marijuana (Cannabis)	SS				
			Cocaine (Cocaine)	SS				
			Methylenedioxyamphet amine					
			(Methylenedioxyamphe tamine)	SS				

Date:06/21/04ISR Number: 4397458-3Report Type:Periodic Company Report #USA-2004-0012932 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride)	PS				
			Marijuana (Cannabis)	SS				
			Cocaine (Cocaine)	SS				
			Methylenedioxyamphet amine (Methylenedioxyamphe tamine)	SS				

Date:06/21/04ISR Number: 4397459-5Report Type:Periodic Company Report #USA-2004-0012933 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride)	PS				
			Marijuana (Cannabis)	SS				
			Cocaine (Cocaine)	SS				
			Methylenedioxyamphet amine (Methylenedioxyamphe tamine)	SS				

21-Jul-2006 10:28 AM

Page: 140

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/21/04ISR Number: 4397461-3Report Type:Periodic Company Report #USA-2004-0012934 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride)	PS				
			Marijuana (Cannabis)	SS				
			Cocaine(Cocaine)	SS				
			Methylenedioxyamphet amine (Methylenedioxyamphe tamine)	SS				

Date:06/21/04ISR Number: 4397464-9Report Type:Periodic Company Report #USA-2004-0012935 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone					

Hydrochloride) PS  
Marijuana (Cannabis) SS  
Cocaine (Cocaine) SS  
Methylenedioxyamphet  
amine  
(Methylenedioxyampe  
tamine) SS

Date:06/21/04ISR Number: 4397467-4Report Type:Periodic Company Report #USA-2004-0012936 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride) PS Marijuana (Cannabis) SS Cocaine (Cocaine) SS Methylene Dioxyamphetamine (Methylenedioxyampe tamine) SS					

Date:06/21/04ISR Number: 4397468-6Report Type:Periodic Company Report #USA-2004-0012937 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride) PS Marijuana (Cannabis) SS Cocaine (Cocaine) SS Methylenedioxyamphet amine (Methylenedioxyampe tamine) SS					

21-Jul-2006 10:28 AM

Page: 141

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/21/04ISR Number: 4397472-8Report Type:Periodic Company Report #USA-2004-0012938 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride) PS Marijuana (Cannabis) SS Cocaine (Cocaine) SS Methylenedioxyamphet					



amine  
(Methylenedioxyamphe  
tamine) SS

Date:06/21/04ISR Number: 4397487-XReport Type:Periodic Company Report #USA-2004-0012944 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride)	PS				
			Marijuana (Cannabis)	SS				
			Cocaine (Cocaine)	SS				
			Methylenedioxyamphet amine (Methylenedioxyamphe tamine)	SS				

Date:06/21/04ISR Number: 4397490-XReport Type:Periodic Company Report #USA-2004-0012945 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride)	PS				
			Marijuana (Marijuana)	SS				
			Cocaine (Cocaine)	SS				
			Methylenedioxyamphet amine (Methylenedioxyamphe tamine)	SS				

Date:06/21/04ISR Number: 4397491-1Report Type:Periodic Company Report #USA-2004-0012946 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride)	PS				
			Marijuana (Cannabis)	SS				
			Cocaine (Cocaine)	SS				
			Methylenedioxyamphet amine (Methylenedioxyamphe tamine)	SS				

Date:06/21/04ISR Number: 4397492-3Report Type:Periodic Company Report #USA-2004-0012947 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride)	PS				
			Marijuana (Cannabis)	SS				
			Cocaine (Cocaine)	SS				
			Methylenedioxyamphet amine					
			(Methylenedioxyamphe tamine)	SS				

Date:06/21/04ISR Number: 4397495-9Report Type:Periodic Company Report #USA-2004-0012948 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride)	PS				
			Marijuana (Cannabis)	SS				
			Cocaine (Cocaine)	SS				
			Methylenedioxyamphet amine					
			(Methylenedioxyamphe tamine)	SS				

Date:06/21/04ISR Number: 4397497-2Report Type:Periodic Company Report #USA-2004-0012949 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride)	PS				
			Marijuana (Cannabis)	SS				
			Cocaine (Cocaine)	SS				
			Methylenedioxyamphet amine					
			(Methylenedioxyamphe tamine)	SS				

Date:06/21/04ISR Number: 4397499-6Report Type:Periodic Company Report #USA-2004-0012950 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride)	PS				
			Marijuana (Cannabis)	SS				
			Cocaine (Cocaine)	SS				
			Methylenedioxyamphet amine					
			Methylenedioxyamphet					

amine) SS

21-Jul-2006 10:28 AM

Page: 143

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/21/04ISR Number: 4397501-1Report Type:Periodic Company Report #USA-2004-0012951 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride)	PS				
			Marijuana (Cannabis)	SS				
			Cocaine (Cocaine)	SS				
			Methylenedioxyamphet amine (Methylenedioxyamphe tamine)	SS				

Date:06/21/04ISR Number: 4397504-7Report Type:Periodic Company Report #USA-2004-0012952 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride)	PS				
			Marijuana (Cannabis)	SS				
			Cocaine (Cocaine)	SS				
			Methylenedioxyamphet amine (Methylenedioxyamphe tamine)	SS				

Date:06/21/04ISR Number: 4397507-2Report Type:Periodic Company Report #USA-2004-0012953 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride)	PS				
			Marijuana (Cannabis)	SS				
			Cocaine (Cocaine)	SS				
			Methylenedioxyamphet amine (Methylenedioxyamphe tamine)	SS				

Date:06/21/04ISR Number: 4397510-2Report Type:Periodic Company Report #USA-2004-0012954 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride)	PS				
			Marijuana (Cannabis)	SS				
			Cocaine (Cocaine)	SS				
			Methylenedioxyamphetamine (Methylenedioxyamphetamine)	SS				

21-Jul-2006 10:28 AM

Page: 144

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/21/04ISR Number: 4397515-1Report Type:Periodic Company Report #USA-2004-0012955 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride)	PS				
			Marijuana (Cannabis)	SS				
			Cocaine (Cocaine)	SS				
			Methylenedioxyamphetamine (Methylenedioxyamphetamine)	SS				

Date:06/21/04ISR Number: 4397518-7Report Type:Periodic Company Report #USA-2004-0012966 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride)	PS				
			Marijuana (Cannabis)	SS				
			Cocaine (Cocaine)	SS				
			Methylenedioxyamphetamine (Methylenedioxyamphetamine)	SS				

Date:06/21/04ISR Number: 4397520-5Report Type:Periodic Company Report #USA-2004-0012967 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					

Other (Oxycodone Hydrochloride) PS  
 Marijuana (Cannabis) SS  
 Cocaine (Cocaine) SS  
 Methylenedioxyamphet  
 amine  
 (Methylenedioxyamphe  
 tamine) SS

Date:06/21/04ISR Number: 4397521-7Report Type:Periodic Company Report #USA-2004-0012968 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride) PS Marijuana (Cannabis) SS Cocaine (Cocaine) SS Methylenedioxyamphet amine (Medhylenedioxyamphe tamine) SS					

21-Jul-2006 10:28 AM

Page: 145

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/21/04ISR Number: 4397523-0Report Type:Periodic Company Report #USA-2004-0012969 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride) PS Marijuana (Cannabis) SS Cocaine (Cocaine) SS Medhylenedioxyamphet amine (Methylenedioxyamphe tamine) SS					

Date:06/21/04ISR Number: 4397530-8Report Type:Periodic Company Report #USA-2004-0012544 Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose Multiple Drug Overdose	Health Professional	Oxycontin Tablets (Oxycodone Hydrochloride) PS		UNKNOWN UNKNOWN		40 MG, UNK,	
	Other		Hydrocodone					

Bitartrate (Similar To Ind 59,175) (Hydrocodone Bitartrate)	SS	UNKNOWN	UNK, UNK, UNK, UNKNOWN
Cannabis (Cannabis)	SS	UNKNOWN	UNK UNK, UNK, UNKNOWN
Propoxyphene (Dextropropoxyphene)	SS	UNKNOWN	UNK UNK, UNK, UNKNOWN
Alprazolam (Alprazolam)	SS	UNKNOWN	UNK UNK, UNK, UNKNOWN
Oxazepam (Oxazepam)	SS	UNKNOWN	UNK UNK, UNK, UNKNOWN
Temazepam (Temazepam)	SS	UNKNOWN	UNK UNK, UNK, UNKNOWN
Acetaminophen (Paracetamol)	SS	UNKNOWN	UNK UNK, UNK, UNKNOWN
Lidocaine (Lidocaine)	SS	UNKNOWN	UNK UNK, UNK, UNKNOWN
Meperidine Hydrochloride (Pethidine Hydrochloride)	SS	UNKNOWN	UNK UNK, UNK, UNKNOWN

Date:06/21/04ISR Number: 4397745-9Report Type:Periodic Company Report #USA-2004-0013633 Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Multiple Drug Overdose Accidental	Health Professional Other	Oxycodone Hydrochloride (Similar To Nda					

21-Jul-2006 10:28 AM

Page: 146

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

20-553) (Oxycodone Hydrochloride) PS  
 Carisoprodol (Carisoprodol) SS  
 Cocaine (Cocaine) SS  
 Marijuana (Cannabis) SS  
 Meprobamate (Meprobamate) SS  
 Carbon Monoxide SS

Date:06/21/04ISR Number: 4397826-XReport Type:Periodic Company Report #USA-2004-0013866

Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Abuser	Consumer	Oxycontin Tablets					
Other	Multiple Drug Overdose	Health Professional	(Oxycodone Hydrochloride)	PS				
	Accidental	Other	Marijuana (Cannabis)	SS				

Date:06/21/04ISR Number: 4397869-6Report Type:Periodic Company Report #USA-2004-0012524 Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride)	PS				
			Cocaine (Cocaine)	SS				
			Marijuana (Cannabis)	SS				

Date:06/21/04ISR Number: 4397870-2Report Type:Periodic Company Report #USA-2004-0012525 Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride)	PS				
			Cocaine (Cocaine)	SS				
			Marijuana (Cannabis)	SS				

Date:06/21/04ISR Number: 4398032-5Report Type:Periodic Company Report #USA-2003-0009147 Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Consumer	Oxycontin Tablets					
Other	Drug Abuser	Health Professional	(Oxycodone Hydrochloride)	PS				
	Multiple Drug Overdose	Other	Cocaine (Cocaine)	SS				
	Accidental		Cannabis (Cannabis)	SS				
			Caffeine (Caffeine)	SS				
			Codeine (Codeine)	SS				
			Paroxetine (Paroxetine)	SS				
			Citalopram (Citalopram)	SS				
			Nicotine (Nicotine)	SS				
			Metamfetamine (Metamfetamine)	SS				
			Oxymorphone					

21-Jul-2006 10:28 AM

Page: 147

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

(Oxymorphone) SS  
Clonazepam C

Paxil C

Date:06/21/04ISR Number: 4398319-6Report Type:Periodic Company Report #USA-2004-0012473 Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin					
		Other	Hydrochloride (Similar To Nda 20-553) (Oxycodone Hydrochloride) PS Hydrocodone Bitartrate (Similar To Ind 59,175) (Hydrocodone Bitartrate) SS Cocaine (Cocaine) SS Valium (Diazepam) SS Ambien (Zolpidem Tartrate) SS Marijuana (Cannabis) SS					

Date:06/21/04ISR Number: 4398854-0Report Type:Periodic Company Report #USA-2003-0007704 Age:27 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Abuser	Health	Oxycodone					
Other	Multiple Drug Overdose Accidental	Professional Other	Hydrochloride (Similar To Nda 20-553) Oxycodone Hydrochloride PS Morphine Sulfate (Similar To Nda 19-516) (Morphine Sulfate) SS Tramadol (Tramadol) SS Cocaine (Cocaine) SS Diazepam (Diazepam) SS Caffeine (Caffeine) SS Nicotine (Nicotine) SS Lidocaine (Lidocaine) SS Xanax (Alprazolam) SS Cannabis (Cannabis) SS Salicylates (Salicylates) SS					

Date:06/21/04ISR Number: 4398879-5Report Type:Periodic Company Report #USA-2003-0007197 Age:27 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					
		Professional Other	Hydrochloride Oxycodone Hydrochloride) PS			MG		



Hydrocodone  
Bitartrate

21-Jul-2006 10:28 AM

Page: 148

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

(Hydrocodone  
Bitartrate) SS  
Carisoprodol  
(Carisoprodol) SS  
Meprobamate  
(Meprobamate) SS  
Ethanol (Ethanol) SS  
Nicotine (Nicotine) SS  
Propoxyphene  
(Dextropropoxyphene  
) SS  
Amitriptyline  
(Amitriptyline) SS  
Marijuana (Cannabis) SS  
  
Valium (Dizaepam) SS  
Zoloft (Sertraline  
Hydrochloride) SS  
Caffeine (Caffeine) SS  
Aventyl  
(Nortriptyline  
Hydrochloride) SS

RESPIRATORY  
(INHALATION) INHALATION

Date:06/21/04ISR Number: 4399077-1Report Type:Periodic Company Report #2012238

Age:17 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose Multiple Drug Overdose	Consumer Health Professional Other	Oxycontin Tablets 10 Mg (Oxycodone Hydrochloride) PS Hydrocodone Bitartrate (Similar To Ind 59,175) (Hydrocodone Bitartrate) SS Methylenedioxyamphet amine (Methylenedioxyamphe tamine) SS Cannabis (Cannabis) SS Metamfetamine (Metamfetamine) SS Caffeine (Caffeine) SS Atracurium (Atracurium) SS			ORAL ORAL		

Date:06/21/04ISR Number: 4399088-6Report Type:Periodic Company Report #2012847 Age:15 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Consumer	Oxycontin Tablets	10				
	Victim Of Homicide	Other	Mg (Oxycodone Hydrochloride)	PS				
			Marijuana (Cannabis)	SS				

21-Jul-2006 10:28 AM

Page: 149

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/21/04ISR Number: 4399096-5Report Type:Periodic Company Report #2014261 Age:30 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Consumer	Oxycontin Tablets					
Hospitalization -	Chills	Health	160 Mg (Oxycodone Hydrochloride)	PS		ORAL	160 MG,	
Initial or Prolonged	Diarrhoea	Professional				DAILY, ORAL		
Other	Drug Abuser	Other						
	Drug Dependence		Marijuana (Cannabis)	SS				
	Drug Withdrawal Syndrome		Zestril	C				
	Pruritus							
	Vomiting							

Date:06/21/04ISR Number: 4399108-9Report Type:Periodic Company Report #KII-2000-0004617 Age:26 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Abuser	Health	Oxycontin Tablets					
	Polysubstance Abuse	Professional	(Oxycodone Hydrochloride)	PS			80 MG, SEE	
		Company Representative				TEXT,		
			Ethanol (Ethanol)	SS		ORAL	ORAL	
			Marijuana (Cannabis)	SS		RESPIRATORY		
					(INHALATION)	INHALATION		
			Cocaine (Cocaine)	SS				

Date:06/21/04ISR Number: 4399190-9Report Type:Periodic Company Report #USA-2003-0008819 Age:29 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization -	Abdominal Pain Upper
Initial or Prolonged	Agitation
Other	Asthenia
	Cold Sweat
	Confusional State
	Decreased Appetite

Depression  
 Diarrhoea  
 Drug Abuser  
 Drug Dependence  
 Drug Tolerance  
 Drug Withdrawal  
 Convulsions  
 Drug Withdrawal Syndrome  
 Fatigue  
 Gastroenteritis  
 Hallucination  
 Headache  
 Hyperhidrosis  
 Ill-Defined Disorder  
 Insomnia  
 Irritability  
 Mood Swings  
 Muscle Spasms  
 Myalgia  
 Nausea  
 Nervousness  
 Pain  
 Paranoia  
 Polysubstance Abuse

21-Jul-2006 10:28 AM

Page: 150

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Disorder	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Suicidal Ideation							
Temperature Regulation							
Tremor	Consumer	Oxycontin Tablets					
Vomiting	Health	(Oxycodone					
Weight Decreased	Professional	Hydrochloride)	PS			SEE TEXT	
	Other	Heroin (Diamorphine) SS					
		Marijuana (Cannabis) SS					
		Roxicodone					
		(Oxycodone					
		Hydrochloride) SS		ORAL	15 MG, ORAL		
		Lorcet (Paracetamol,					
		Hydrocodone					
		Bitartrate) SS					
		Codeine (Codeine) SS					
		Neurontin C					
		Flexeril C					
		Zoloft C					
		Efexor C					
		Motrin C					
		Percocet C					
		Medrol C					

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Polysubstance Abuse Other	Consumer	Oxycontin Tablets (Oxycodone Hydrochloride) PS			MG		
			Oxycodone Hydrochloride (Similar To Nda 20-552) (Oxycodone Hydrochloride) SS					
			Marijuana (Cannabis) SS					

Date:06/21/04ISR Number: 4399435-5Report Type:Periodic Company Report #USA-2004-0013537 Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Polysubstance Abuse Other	Consumer	Oxycodone Hydrochloride (Similar To Nda 20-553) (Oxycodone Hydrochloride) PS					
			Morphine Sulfate (Similar To Nda 19-516) (Morphine Sulfate) SS					
			Hydrocodone Bitartrate (Similar To Ind 59,175) (Hydrocodone Bitartrate) SS					
			Marijuana (Cannabis) SS					
			Cocaine (Cocaine) SS					

21-Jul-2006 10:28 AM

Page: 151

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/21/04ISR Number: 4399645-7Report Type:Periodic Company Report #USA-2004-0012871 Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Marijuana (Cannabis) Crack Cocaine (Cocaine) SS	PS				

Date:06/21/04ISR Number: 4399693-7Report Type:Periodic Company Report #USA-2004-0012737 Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser	Consumer	Oxycontin Tablets (Oxycodone Hydrochloride) PS					

Marijuana (Cannabis) SS

Date:06/21/04ISR Number: 4405083-0Report Type:Periodic Company Report #USA-2004-0014084 Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Polysubstance Abuse Other	Consumer (Oxycodone Hydrochloride) Marijuana (Cannabis) SS	Oxycontin Tablets PS			MG,		

Date:06/21/04ISR Number: 4415521-5Report Type:Periodic Company Report #USA-2003-0011708 Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Multiple Drug Overdose Accidental	Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-553) (Oxycodone Hydrochloride) PS Hydrocodone Bitartrate (Similar To Ind 59,175) (Hydrocodone Bitartrate) SS Olanzapine (Olanzapine) SS Alprazolam (Alprazolam ) SS Oxymorphone (Oxymorphone) SS Meperidone Hydrochloride (Pethidine Hydrochloride) SS Cannabis (Cannabis) SS Quinidine (Quinidine) SS Atenolol (Atenolol) SS Quinine (Quinine) SS					

21-Jul-2006 10:28 AM

Page: 152

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/21/04ISR Number: 4415609-9Report Type:Periodic Company Report #USA-2003-0011837 Age:31 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycodone					

Multiple Drug Overdose  
Other

Professional Hydrochloride  
(Similar To Nda  
20-553) (Oxycodone  
Hydrochloride) PS  
Alprazolam  
(Alprazolam) SS  
Cocaine (Cocaine) SS  
Sertraline  
(Sertraline) SS  
Acetaminophen  
(Paracetamol) SS  
Cannabis (Cannabis) SS  
Carisoprodol  
(Carisoprodol) SS  
Meprobamate  
(Meprobamate) SS  
Olanzapine  
(Olanzapine) SS  
Lorazepam  
(Lorazepam) SS

Date:06/23/04ISR Number: 4388099-2Report Type:Expedited (15-DaCompany Report #KII-2004-0011425

Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Agitation Blood Alcohol Increased Blood Alkaline Phosphatase Increased Blood Pressure Systolic Increased Cerebrovascular Accident Coma Convulsion Drug Screen Positive Heart Rate Decreased Respiratory Rate Decreased Respiratory Rate Increased Somnolence	Study Professional Health Other	Morphine Sulfate (Similar To Nda 19-516) (Morphine Sulfate) Benzodiazepine Derivatives () Acetaminophen W/Hydrocodone Bitartrate (Paracetamol, Hydrocodone Ethanol (Ethanol) Acetylsalicylic Acid (Acetylsalicylic Acid) Marijuana (Cannabis)	PS SS SS SS SS SS		ORAL ORAL ORAL ORAL ORAL ORAL ORAL ORAL	ORAL ORAL ORAL ORAL ORAL ORAL ORAL ORAL	

Date:07/02/04ISR Number: 4392032-7Report Type:Expedited (15-DaCompany Report #2012272

Age:42 YR Gender:Male I/FU:F

Outcome	PT
Death	Accidental Overdose
Hospitalization - Initial or Prolonged Other	Asthenia Back Pain Drug Abuser
Required Intervention to Prevent Permanent Impairment/Damage	Drug Toxicity Erectile Dysfunction Haematemesis Haemorrhage Headache

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Iron Deficiency Anaemia  
Mallory-Weiss Syndrome

Respiratory Arrest	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Tachycardia	Consumer	Oxycontin					
Tooth Disorder	Health	Tablets(Oxycodone					
Tooth Extraction	Professional	Hydrochloride) Cr					
	Other	Tablet				10 MG, BID	
		PS				; 20 MG ;	
						40 MG	
		Diazepam(Diazepam)	SS				
		Oxazepam(Oxazepam)	SS				
		Temazepam(Temazepam)	SS				
		Lorazepam(Lorazepam)	SS				
		Cannaboids(Cannabis)	SS				
		Diphenhydramine					
		Hydrochloride(Diphen					
		hydramine					
		Hydrochloride)	SS				
		Gabapentin(Gabapenti	n)				
			SS				
		Claritin(Loratadine)	C				
		Zoloft(Sertraline					
		Hydrochloride)	C				
		Altace(Ramipril)	C				
		Allopurinol	C				
		Depakote(Valproate					
		Semisodium)	C				
		Soma (Carisoprodol)	C				
		Relafen (Nabumetone)	C				

Date:07/06/04ISR Number: 4394668-6Report Type:Expedited (15-DaCompany Report #HQWYE652324JUN04

Age:35 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Effect Decreased Drug Interaction	Foreign Health Professional Other	Pantoloc (Pantoprazole, Tablet, Delayed Release) PS			ORAL	40 MG 1X PER 1 DAY ORAL	
			Marijuana (Cannabis	SS			"SMOKING 1/2 OZ. AND EATING 1/2 OZ."	
			Effexor (Venlafaxine Hydrochloride)	C				

Date:07/14/04ISR Number: 4401701-1Report Type:Expedited (15-DaCompany Report #USA-2003-0008901

Age:45 YR Gender:Male I/FU:F

Outcome PT  
 Hospitalization - Anger  
 Initial or Prolonged Anxiety  
 Other Back Pain  
 Bronchitis Acute  
 Burning Sensation  
 Carpal Tunnel Syndrome  
 Cough  
 Depression Suicidal  
 Diabetic Neuropathy

21-Jul-2006 10:28 AM

Page: 154

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Drug Abuser	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Drug Dependence	Consumer	Oxycontin					
Drug Withdrawal Syndrome	Health	Tablets(Oxycodone Hydrochloride) Cr					
Hypoaesthesia	Professional	Tablet PS					
Intervertebral Disc Degeneration	Other	Perocet (Oxycodonehydrochloride, Paracetamol) SS		ORAL	5 MG, HS,		
Irritability		Lortab (Paracetamol, Hydrocodone Bitartrate) SS		ORAL			
Lethargy		Marijuana (Cannabis) SS					
Nasopharyngitis		Restoril (Temazepam) C					
Nervousness		Trazadone (Trazadone) C					
Osteoarthritis		Phenobarbital (Phenobarbital) C					
Pain		Gliburide (Glibenclamide) C					
Paraesthesia		Ativan (Lorazepam) C					
Polysubstance Abuse		Effexor (Venlafaxine Hydrochloride) C					
Self-Injurious Ideation							
Tremor							

Date:07/16/04ISR Number: 4406641-XReport Type:Expedited (15-DaCompany Report #REFE00204002334 Age:60 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Pressure Decreased	Foreign	Cannador (Cannador)	PS		ORAL	10 MG DAILY	
	Circulatory Collapse	Study				PO, 10 MG		
	Pulse Absent	Health				DAILY PO		
	Sinus Bradycardia	Professional	Baclofen (Baclofen)	SS		ORAL	30 MG DAILY	
		Other				PO		

Date:07/16/04ISR Number: 4406643-3Report Type:Expedited (15-DaCompany Report #REFE00204002335 Age:49 YR Gender:Male I/FU:F



Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Duodenal Ulcer	Foreign	Cannador	(Cannador)	PS	ORAL	25 MG	DAILY
Initial or Prolonged	Gastritis	Study				PO, 25 MG		
		Health				DAILY PO		
		Professional	Baclofen		C			
		Other	Zolpidem Tartrate		C			
			Co-Proxamol		C			

Date:07/19/04ISR Number: 4402663-3Report Type:Expedited (15-DaCompany Report #KII-2004-0011874

Age:20 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization -	Aggression
Initial or Prolonged	Agitation
Other	Blood Pressure Systolic
	Decreased
	Cardiac Enzymes Increased
	Coma
	Cyanosis

21-Jul-2006 10:28 AM

Page: 155

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Feeling Abnormal  
Hypertension

Miosis	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Overdose	Study	Morphine Sulfate					
Respiratory Rate	Health	(Similar To Nda					
Decreased	Professional	19-516)(Morphine					
Tachycardia	Other	Sulfate) Unknown	PS		ORAL	ORAL	
		Cannabis (Cannabis)	SS				
		Benzodiazepine					
		Derivatives()	SS				

Date:07/29/04ISR Number: 4443729-1Report Type:Periodic Company Report #USA-2004-0014564

Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Health	Morphine Sulfate					
		Professional	(Similar To Nda					
		Other	19-516) (Morphine					
			Sulfate)	PS				
			Fluoxetine	SS				
			Neurontin					
			(Gabapentin)	SS				
			Trazodone	SS				
			Cannabis	SS				
			Alprazolam	SS				
			Temazepam`	SS				
			Oxazepam	SS				
			Metoprolol	SS				

Dextromethorphan SS  
 Acetaminophen  
 (Paracetamol) SS  
 Propoxyphene  
 (Dextropropoxyphene) SS

Date:07/29/04ISR Number: 4444008-9Report Type:Periodic Company Report #USA-2003-0006704 Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Anxiety Constipation Depression	Consumer Other	Ms Contin Tablets (Morphine Sulfate)	PS		ORAL	60 MG, BID,	
Drug Abuser			Cocaine (Cocaine)	SS		ORAL	SEE TEXT	
Drug Dependence			Marijuana (Cannabis)	SS			SEE TEXT	
Drug Tolerance			Celebrex	C				
Drug Withdrawal Syndrome			Remeron	C				
Fatigue			Prednisone	C				
Night Sweats			Arava	C				
Nodule			Elavil	C				
Oedema Peripheral			Methotrexate	C				
Pain			Folic Acid	C				
Sleep Disorder			Vistapril	C				
Suicidal Ideation			Clonidine	C				
Weight Decreased			Toradol	C				
Weight Increased								

21-Jul-2006 10:28 AM

Page: 156

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:07/29/04ISR Number: 4444081-8Report Type:Periodic Company Report #US-JNJFOC-20040203721 Age:19 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Agitation Catatonia Drug Abuser Sedation	Health Professional	Risperdal (Risperidone)	PS		ORAL	4 MG, IN 1 DAY, ORAL	
			Cannabis (Cannabis)	SS				
			Lorazepam (Lorazepam)	SS			9 MG, IN 1 DAY; 3 MG, IN 1 DAY	
			Divalproex (Valproate Semisodium)	SS				

Date:07/29/04ISR Number: 4444312-4Report Type:Periodic Company Report #USA-2003-0011565 Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Intentional Overdose Multiple Drug Overdose Other	Health Professional 19-516) (Morphine Sulfate) Venlafaxine (Venlafaxine) Diphenhydramine (Diphenhydramine) Cannabis (Cannabis) Salicylates (Salicylates) Gabapentin (Gabapentin) Valproic Acid (Valproic Acid) Nicotine (Nicotine)	Morphine Sulfate (Similar To Nda 19-516) (Morphine Sulfate) PS Venlafaxine (Venlafaxine) SS Diphenhydramine (Diphenhydramine) SS Cannabis (Cannabis) SS Salicylates (Salicylates) SS Gabapentin (Gabapentin) SS Valproic Acid (Valproic Acid) SS Nicotine (Nicotine) SS					

Date:07/29/04ISR Number: 4444313-6Report Type:Periodic Company Report #USA-2003-0011569 Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health Professional Other (Similar To Nda 19-516) (Morphine Sulfate) PS Marijuana (Cannabis) Ethanol (Ethanol) Nicotine (Nicotine)	Morphine Sulfate (Similar To Nda 19-516) (Morphine Sulfate) PS Marijuana (Cannabis) SS Ethanol (Ethanol) SS Nicotine (Nicotine) SS					

Date:07/29/04ISR Number: 4444325-2Report Type:Periodic Company Report #USA-2003-0011725 Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health Professional Other (Similar To Nda 19-516) (Morphine Sulfate) PS Oxycodone	Morphine Sulfate (Similar To Nda 19-516) (Morphine Sulfate) PS Oxycodone					

21-Jul-2006 10:28 AM

Page: 157

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Hydrochloride  
(Similar To Nda  
20553) (Oxycodone  
Hydrochloride) SS  
Cannabis (Cannabis) SS

Date:08/04/04ISR Number: 4420872-4Report Type:Expedited (15-DaCompany Report #2004EU001424

Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Abuser	Foreign	Prograf (Tacrolimus)					
Other	Drug Interaction	Health	Formulation Unknown	PS			9.00 MG, BID.	
	Hyperthyroidism	Professional	Cannabis (Cannabis)	SS				
	Immunosuppressant Drug	Other	Cellcept					
	Level Increased		(Mycophenolate					
	Overdose		Mofetil) SS			D		
			Corticosteroids ( )	SS		D		

Date:08/06/04ISR Number: 4422478-XReport Type:Expedited (15-DaCompany Report #KII-2004-0012650

Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anoxic Encephalopathy	Study	Oxycontin Tablets					
	Blood Ph Decreased	Health	(Oxycodone					
	Blood Pressure Decreased	Professional	Hydrochloride) Cr					
	Drug Screen Positive	Other	Tablet	PS		ORAL		ORAL
	Heart Rate Increased		Cocaine (Cocaine)	SS				
	Paralysis		Ethanol (Ethanol)	SS		ORAL		ORAL
	Pco2 Increased		Marijuana (Cannabis)	SS				
	Pneumonia Aspiration		Benzodiazepine					
			Derivatives()	SS		ORAL		ORAL

Date:08/09/04ISR Number: 4425428-5Report Type:Expedited (15-DaCompany Report #KII-2004-0012664

Age:38 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization -	Acidosis
Initial or Prolonged	Agitation
Other	Blood Creatine
	Phosphokinase Increased
	Blood Pressure Diastolic
	Decreased
	Body Temperature
	Decreased
	Coma
	Depressed Level Of
	Consciousness
	Drug Screen Positive
	Gastrointestinal
	Haemorrhage
	Heart Rate Increased
	Hepatotoxicity
	Hyperkalaemia
	Lethargy
	Liver Function Test
	Abnormal
	Occult Blood Positive
	Poisoning Deliberate
	Pyrexia

Freedom Of Information (FOI) Report

Renal Failure  
Somnolence

Transaminases Increased	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Study Health Professional Other	Oxycontin Tablets (Oxycodone Hydrochloride) Cr Tablet	PS	ORAL	ORAL			
	Benzodiazepine Derivatives	SS	ORAL	ORAL			
	Effexor (Venlafaxine Hydrochloride)	SS	ORAL	ORAL			
	Trazodone (Trazodone)	SS	ORAL	ORAL			
	Valproic Acid (Valproic Acid)	SS	ORAL	ORAL			
	Marijuana (Cannabis)	SS					

Date:08/12/04ISR Number: 4427511-7Report Type:Expedited (15-DaCompany Report #USA-2003-0008901

Age:45 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Anger Back Pain Bronchitis Acute	Consumer Health Professional Other	Oxycontin Tablets (Oxycodone Hydrochloride) Cr Tablet	PS		ORAL	SEE TEXT,	
	Burning Sensation Dependence Depression Depression Suicidal Device Migration Diabetic Neuropathy Disease Recurrence Drug Dependence Drug Withdrawal Syndrome Hypoaesthesia Inadequate Analgesia Intervertebral Disc Degeneration Irritability Lethargy Nasopharyngitis Nervousness Pain Paraesthesia Polysubstance Abuse Pseudarthrosis Radicular Pain Self-Injurious Ideation Suicidal Ideation Tremor		Percocet(Oxycodone Hydrochloride, Paracetamol)	SS		ORAL	5 MG, HS,	
			Lortab(Paracetamol, Hydrocodone Bitartrate)	SS		ORAL		
			Marijuana(Cannabis)	SS				
			Restoril (Temazepam)	C				
			Trazodone	C				
			Phenobarbital	C				
			Glyburide (Glibenclamide)	C				
			Ativan (Lorazepam)	C				
			Effexor (Venlafaxine Hydrochloride)	C				
			Valium (Diazepam)	C				
			Ambien (Zolpidem Tartrate)	C				

Date:08/16/04ISR Number: 4428476-4Report Type:Expedited (15-DaCompany Report #KII-2004-0012888

Age:15 YR Gender:Female I/FU:I

Outcome PT  
 Hospitalization - Alanine Aminotransferase  
 Initial or Prolonged Increased  
 Other Anoxic Encephalopathy  
 Aspartate  
 Aminotransferase

21-Jul-2006 10:28 AM

Page: 159

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Increased	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Blood Bicarbonate							
Decreased							
Blood Calcium Decreased	Study	Morphine Sulfate					
Blood Creatine Phosphokinase Increased	Health	(Similar To Nda					
Coma	Professional	19-516) (Morphine					
Cough	Other	Sulfate) PS					
Electroencephalogram Abnormal		Cocaine(Cocaine)	SS				
Fibrin D Dimer Increased		Ethanol(Ethanol)	SS				
Haemoglobin Decreased		Heroin(Diamorphine)	SS				
Hyperpyrexia		Marijuana(Cannabis)	SS				
Hypertension							
Hypokinesia							
Hyporeflexia							
Hypothermia							
Leukoencephalopathy							
Movement Disorder							
Multiple Drug Overdose							
Muscle Rigidity							
Pco2 Decreased							
Posturing							
Procedural Complication							
Protein Total Decreased							
Prothrombin Time							
Prolonged							
Respiratory Rate							
Increased							
Serotonin Syndrome							
Tachycardia							
White Blood Cell Count							
Increased							

Date:08/23/04ISR Number: 4433134-6Report Type:Expedited (15-DaCompany Report #KII-2004-0013024

Age:47 YR Gender:Male I/FU:I

Outcome PT  
 Hospitalization - Anion Gap Increased  
 Initial or Prolonged Apnoea  
 Other Blood Bicarbonate  
 Decreased  
 Blood Creatinine

Increased  
 Blood Glucose Increased  
 Blood Ph Decreased  
 Blood Urine Present  
 Body Temperature  
 Increased  
 Coma  
 Dialysis  
 Hyperoxaluria  
 Hypoxia  
 Multiple Drug Overdose  
 Pco2 Decreased  
 Polysubstance Abuse  
 Salivary Hypersecretion  
 Specific Gravity Urine  
 Abnormal  
 Status Epilepticus  
 White Blood Cell Count

21-Jul-2006 10:28 AM

Page: 160

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Increased

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Study	Oxycontin	PS				
Health	Ethylene Glycol	SS		ORAL	ORAL	
Professional	Marijuana (Cannabis)	SS		RESPIRATORY		
Other			(INHALATION)	INHALATION		
	Lamictal (Lamotrigine)	SS		ORAL	ORAL	

Date:09/01/04ISR Number: 4443221-4Report Type:Expedited (15-DaCompany Report #USA-2004-0015607 Age:22 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accident	Consumer	Oxycontin					
Other	Accidental Overdose	Health	Tablets(Oxycodone					
	Loss Of Consciousness	Professional	Hydrochloride) Cr					
	Multiple Drug Overdose	Other	Tablet	PS		MG		
	Polysubstance Abuse		Ketamine (Ketamine)	SS				
			Diazepam (Diazepam)	SS				
			Marijuana (Cannabis)	SS				
			Cocaine (Cocaine)	SS				

Date:09/03/04ISR Number: 4440472-XReport Type:Expedited (15-DaCompany Report #PHBS2004IT11483 Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Agitation	Health	Clozapine	PS	Novartis Sector:			
Initial or Prolonged	Alanine Aminotransferase	Professional			Pharma	UNKNOWN	300 mg/d	730 DAY
	Increased		Clozapine	SS	Novartis Sector:			

Aspartate		Pharma	UNKNOWN	1000 mg/d	
Aminotransferase	Venlafaxine	SS	UNKNOWN	150 mg/d	730 DAY
Increased	Venlafaxine	SS	UNKNOWN	900 mg/d	
Blood Cannabinoids	Cannabis	SS			
Blood Creatine					
Phosphokinase Increased					
Blood Pressure Abnormal					
Blood Pressure					
Fluctuation					
Coma					
Delirium					
Delusion					
Depression					
Leukocytosis					
Myoglobin Blood Increased					
Neuroleptic Malignant					
Syndrom					
Overdose					
Pyrexia					

Date:09/15/04ISR Number: 4451507-2Report Type:Expedited (15-DaCompany Report #USA-2003-0007534

Age:39 YR Gender:Male I/FU:F

Outcome PT  
 Death Acute Pulmonary Oedema  
 Aspiration  
 Completed Suicide  
 Contusion

21-Jul-2006 10:28 AM

Page: 161

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Gun Shot Wound							
Haemorrhage							
Jaw Fracture	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Laceration	Health	Oxycodone					
Perirenal Haematoma	Professional	Hydrochloride					
Retroperitoneal Haematoma	Other	(Similar To Nda					
Skull Fracture		20-553) (Oxycodone					
Toxicologic Test Abnormal		Hydrochloride)	PS		UNKNOWN	UNK	
	Sertraline						
	(Sertraline)	SS		UNKNOWN	UNK		
	Diazepam (Diazepam)	SS		UNKNOWN	UNK		
	Caffeine (Caffeine)	SS		UNKNOWN	UNK		
	Cannabis (Cannabis)	SS		UNKNOWN	UNK		
	Nicotine (Nicotine)	SS		UNKNOWN	UNK		
	Acetaminophen						
	(Paracetamol)	SS		UNKNOWN	UNK		

Date:09/15/04ISR Number: 4451595-3Report Type:Expedited (15-DaCompany Report #KII-2004-0013275

Age:17 YR Gender:Male I/FU:I



Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Agitation Apnoea Coma Drug Toxicity Drug Withdrawal Syndrome Hypotonia Hypoventilation Hypoxia Laryngospasm Miosis Multiple Drug Overdose Polysubstance Abuse Somnolence	Study Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-553)(Oxycodone Hydrochloride) Benzodiazepine Derivatives() Carisoprodol (Carisoprodol) Aspirin W/Codeine (Codeine Phosphate, Acetylsalicylic Acid) SS Marijuana (Cannabis) Antipsychotics C Trazodone (Trazodone) C Valproic Acid (Valproic Acid) C	PS		ORAL  ORAL  ORAL  ORAL  ORAL  ORAL  ORAL	ORAL	

Date:09/17/04ISR Number: 4452208-7Report Type:Expedited (15-DaCompany Report #CH-JNJFOC-20040902374

Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Coma Diaphragmatic Paralysis Drug Interaction Electromechanical Dissociation Hyperthermia Hypotension Multiple Drug Overdose Respiratory Arrest Serotonin Syndrome Somnolence Suicide Attempt Tachycardia Ventricular Tachycardia		Tramal Benzodiazepine Cannabis Aurorix Seropram Kokain Heroin	PS SS SS I I I I		OROPHARINGEAL UNKNOWN UNKNOWN OROPHARINGEAL OPHTHALMIC INTRAVENOUS NASAL	1.5-3g total dose.	

21-Jul-2006 10:28 AM

Page: 162

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/23/04ISR Number: 4459710-2Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040903506

Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged Other	Abdominal Pain Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Blood Bicarbonate	Literature Health Professional	Acetaminophen (Acetaminophen) Marijuana (Cannabis)	PS SS		RESPIRATORY INHALATION	15-25 GRAMS	

Decreased  
 Blood Creatinine  
 Increased  
 Blood Ph Decreased  
 Bradycardia  
 Brain Herniation  
 Confusional State  
 Encephalopathy  
 Fatigue  
 Haematocrit Increased  
 Hypertension  
 Hypotension  
 International Normalised  
 Ratio Increased  
 Liver Function Test  
 Abnormal  
 Nausea  
 Oral Intake Reduced  
 Overdose  
 Urine Output Decreased

Date:10/14/04ISR Number: 4477770-XReport Type:Expedited (15-DaCompany Report #2004073296 Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cognitive Deterioration	Health	Geodon (Ziprasidone)	PS			160 MG	
	Pain	Professional	Neurontin					
	Paraesthesia	Company	(Gabapentin)	SS				
	Speech Disorder	Representative	Quetiapine Fumarate					
			(Quetiapine Fumarate)	SS		100 MG		
			Cannabis (Cannabis)	SS				

Date:10/21/04ISR Number: 4485940-XReport Type:Expedited (15-DaCompany Report #USA-2004-0016808 Age:22 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Arteriosclerosis Artery	Coronary Health	Oxycontin					
	Blood Ethanol Increased	Professional	Hydrochloride)	Cr				
	Bronchopneumonia	Other	Tablet	PS		MG		
	Drug Interaction		Hydrocodone					
	Drug Screen Positive		(Hydrocodone)	SS		MG		
	Hepatic Steatosis		Ethanol (Ethanol)	SS		L		
	Multiple Drug Overdose		Alprazolam					
			(Alprazolam)	SS		MG		
			Acetaminophen					
			(Paracetamol)	SS		MG		
			Marijuana (Cannabis)	SS				

Oxazepam (Oxazepam) SS  
 Temazepam  
 (Temazepam) SS  
 Ephedrine  
 (Ephedrine) SS  
 Pseudoephedrine  
 (Pseudoephedrine) SS

Date:10/25/04ISR Number: 4489413-XReport Type:Expedited (15-DaCompany Report #2004076997 Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Drug Abuser Drug Screen Positive Hallucination Headache Mood Altered Personality Change Due To A General Medical Condition Psychotic Disorder	Consumer	Unisom Sleepgels (Diphenhydramine) Cannabis (Cannabis)	PS SS		ORAL ONCE, ORAL	20-24 GELS	

Date:10/26/04ISR Number: 4488298-5Report Type:Expedited (15-DaCompany Report #USA-2004-0017339 Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Head Injury Poisoning Polysubstance Abuse Road Traffic Accident	Other	Oxycodone Morphine(Morphine) Valium (Diazepam) Marijuana (Cannabis) Lidocaine (Lidocaine) Tylenol(Paracetamol) Hydrocodone(Hydrocod one)	PS SS SS SS				

Date:10/26/04ISR Number: 4488301-2Report Type:Expedited (15-DaCompany Report #2004065315 Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Drug Exposure During Pregnancy Drug Withdrawal Syndrome Neonatal Maternal Use Of Illicit Drugs Premature Baby	Health Professional Company Representative	Neurontin (Gabapentin) Cannabis (Cannabis) Hydrocodone (Hydrocodone)	PS SS SS		TRANSPLACENTAL MG, 3 IN 1 D), PLACENTAL TRANSPLACENTAL PLACENTAL TRANSPLACENTAL PLACENTAL	2400 MG (800 MG, 3 IN 1	

Date:10/27/04ISR Number: 4490810-7Report Type:Expedited (15-DaCompany Report #USA-2004-0017339 Age:45 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Toxicity	Other	Oxycodone					

Initial or Prolonged Head Injury  
Other Polysubstance Abuse  
Road Traffic Accident

Hydrochloride  
(Similar To Nda  
20-553) (Oxycodone  
Hydrochloride) PS

21-Jul-2006 10:28 AM

Page: 164

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Morphine Sulfate  
(Similar To Nda  
19-516) (Morphine  
Sulfate) SS  
Valium (Diazepam) SS  
Marijuana (Cannabis) SS  
Lidocaine  
(Lidocaine) SS  
Tylenol  
(Paracetamol) SS  
Hydrocodone  
(Hydrocodone) SS

Date:11/03/04ISR Number: 4494875-8Report Type:Expedited (15-DaCompany Report #USA-2004-0017339

Age:45 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Drug Screen Positive	Consumer	Oxycodone					
Initial or Prolonged	Drug Toxicity	Other	Hydrochloride					
Other	Head Injury		(Similar To Nda					
	Incoherent		20-553)(Oxycodone					
	Polysubstance Abuse		Hydrochloride)	PS				
	Road Traffic Accident		Morphine Sulfate					
			(Similar To Nda					
			19-516) (Morphine					
			Sulfate)	SS				
			Valium (Diazepam)	SS				
			Marijuana (Cannabis)	SS				
			Lidocaine					
			(Lidocaine)	SS				
			Tylenol					
			(Paracetamol)	SS				
			Hydrocodone					
			(Hydrocodone)	SS				
			Percocet					
			(Paracetamol,					
			Oxycodone					
			Hydrochloride)	SS				
			Vicodin					
			(Paracetamol,					
			Hydrocodone					
			Bitartrate)	SS				

Date:11/04/04ISR Number: 4495025-4Report Type:Expedited (15-DaCompany Report #2004-BP-10532RO

Age:44 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Abuser Multiple Drug Overdose	Literature	Cocaine Hcl Topical Solution, 10% (Cocaine) PS Methamphetamine SS Marijuana (Cannabis Sativa) SS					

21-Jul-2006 10:28 AM

Page: 165

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/04/04ISR Number: 4495035-7Report Type:Expedited (15-DaCompany Report #2004-BP-10538RO

Age:21 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Abuser Multiple Drug Overdose	Literature	Cocaine Hcl Topical Solution, 10% (Cocaine) PS Methylenedioxymetham phetamine (Methylenedioxymetha mphetamine) SS Marijuana (Cannabis Sativa) SS					

Date:11/04/04ISR Number: 4495349-0Report Type:Expedited (15-DaCompany Report #2004-BP-10507RO

Age:20 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest Drug Abuser Multiple Drug Overdose Intentional	Literature	Cocaine Hcl Topical Solution, 10% (Cocaine) PS Marijuanja (Cannabis Sativa) SS					

Date:11/04/04ISR Number: 4495413-6Report Type:Expedited (15-DaCompany Report #2004-BP-10532RO

Age:44 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Abuser Multiple Drug Overdose Intentional	Literature	Cocaine Hcl Topical Solution, 10% (Cocaine) PS Methamphetamine SS Marijuana (Cannabis Sativa) SS					

Date:11/04/04ISR Number: 4495504-XReport Type:Expedited (15-DaCompany Report #2004-BP-10507RO

Age:20 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Literature	Cocaine Hcl Topical					
	Drug Abuser		Solution, 10%					
	Multiple Drug Overdose		(Cocaine)	PS				
	Intentional		Marijuana (Cannabis Sativa)	SS				

Date:11/05/04ISR Number: 4497981-7Report Type:Expedited (15-DaCompany Report #KII-2004-0013742

Age:39 YR Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Abnormal Behaviour Agitation
	Depressed Level Of Consciousness
	Drug Effect Decreased
	Drug Screen Positive
	Electrocardiogram Qrs Complex Prolonged
	Heart Rate Increased

21-Jul-2006 10:28 AM

Page: 166

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Multiple Drug Overdose	Respiration Abnormal	Treatment Noncompliance	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Study Health Professional Other		Oxycodone Hydrochloride (Similar To Nda 20-553) (Oxycodone Hydrochloride)	PS	ORAL	ORAL			
			Morphine Sulfate (Similar To Nda 19-516) (Morphine Sulfate)	SS	ORAL	ORAL			
			Amitriptyline (Amitriptyline)	SS	ORAL	ORAL			
			Cyclobenzaprine (Cyclobenzaprine)	SS	ORAL	ORAL			
			Cocaine (Cocaine)	SS					
			Marijuana (Cannabis Barbiturates ())	SS	ORAL	ORAL			

Date:11/22/04ISR Number: 4527910-9Report Type:Periodic Company Report #100127

Age:22 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Aggression Anxiety Respiratory Arrest	Health Professional	Testosterone Marijuana	PS SS		IM	1 ML WEEKLY	

Date:12/03/04ISR Number: 4533586-7Report Type:Periodic Company Report #2004047359 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Depression Priapism Scar	Health Professional	Viagra (Sildenafil)	PS		ORAL	100 MG (100 MG, AS NEEDED), ORAL 2 YR	1 YR
		Zoloft (Sertraline)	SS					
		Cannabis (Cannabis)	SS					

Date:12/07/04ISR Number: 4522479-7Report Type:Expedited (15-DaCompany Report #KII-2004-0014145 Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Aspiration Depressed Level Of Consciousness Drug Screen Positive Lung Disorder Lung Infiltration Medication Error Polysubstance Abuse Vomiting	Study Health Professional Other	Oxycontin Tablets (Oxycodone Hydrochloride) Cr Tablet Heroin (Diamorphine) Cannabis (Cannabis)	PS SS SS		RESPIRATORY (INHALATION) RESPIRATORY (INHALATION) RESPIRATORY (INHALATION)	INHALATION INHALATION	

21-Jul-2006 10:28 AM

Page: 167

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/15/04ISR Number: 4530403-6Report Type:Expedited (15-DaCompany Report #USA-2002-0002836 Age:45 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged Other	Alcohol Withdrawal Syndrome Alcoholism Anxiety Back Pain Completed Suicide Cough Dependent Personality Disorder Depression	Consumer Health Professional Other	Oxycontin Tablets 20 Mg (Oxycodone Hydrochloride)Cr Tablet Lorcet (Paracetamol, Hydrocodone Bitartrate) SS Marijuana (Cannabis) Remeron (Mirtazapine) C	PS SS SS		ORAL SEE IMAGE 10 MG		

Drug Abuser	Relafen (Nabumetone) C
Drug Dependence	Neurontin
Drug Ineffective	(Gabapentin) C
Drug Withdrawal Syndrome	Ultram C
Gun Shot Wound	Soma (Carisoprodol) C
Hypoaesthesia	Effexor (Venlafaxine
Impaired Driving Ability	Hydrochloride) C
Inadequate Analgesia	Biaxin
Intentional Drug Misuse	(Clarithromycin) C
Loss Of Consciousness	Xanax (Alprazolam) C
Muscle Spasms	Zanaflex (Tizanidine
Musculoskeletal Stiffness	Hydrochloride) C
Neck Pain	Tranxene
Oxygen Saturation	(Clorazepate
Decreased	Dipotassium) C
Pain	Zoloft (Sertraline
Pain In Extremity	Hydrochloride) C
Paraesthesia	
Personality Disorder	
Polysubstance Abuse	
Pyrexia	
Rhonchi	
Somatoform Disorder	
Temperature Intolerance	
Upper Respiratory Tract	
Infection	
Weight Decreased	
Wheezing	

Date:12/16/04ISR Number: 4530704-1Report Type:Expedited (15-DaCompany Report #DSA\_25435\_2004

Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alcohol Use	Foreign	Temesta	PS		RESPIRATORY		
	Intentional Drug Misuse	Consumer				(INHALATION)	DF IH	
	Polysubstance Abuse	Other	Alcohol	SS		ORAL	PO	
	Sexual Assault Victim		Cannabis	SS		RESPIRATORY		
						(INHALATION)	DF IN	

Date:12/27/04ISR Number: 4541579-9Report Type:Expedited (15-DaCompany Report #USA-2004-0018072

Age:41 YR Gender:Male I/FU:I

Outcome	PT
Death	Apnoea
Other	Cyanosis
	Drug Abuser

21-Jul-2006 10:28 AM

Page: 168

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Drug Toxicity  
Hepatitis Chronic Active



Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Lymphadenopathy		Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Multiple Drug Overdose		Foreign	Morphine Sulfate					
Petechiae		Literature	(Morphine Sulfate)	PS				
Pulmonary Oedema		Health	Duragesic					
Wound		Professional	(Fentanyl)	SS				
	Other	Ethanol						
		(Ethanol)	SS		ORAL	ORAL		
		Amfetamine						
		(Amfetamine)	SS					
		Cannabinoids	SS					

Date:12/27/04ISR Number: 4542242-0Report Type:Expedited (15-DaCompany Report #USA-2004-0018097 Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Gun Shot Wound	Consumer	Oxycodone Hcl Cr					
Other	Polysubstance Abuse	Other	Tablets (Similar To					
			Nda 20-553)					
			(Oxycodone					
			Hydrochloride) Cr	PS				
			Xanax (Alprazolam)	SS				
			Cocaine (Cocaine)	SS				
			Oxymorphone					
			(Oxymorphone)	SS				
			Marijuana (Cannabis)	SS				

Date:01/03/05ISR Number: 4545895-6Report Type:Expedited (15-DaCompany Report #2004118858 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Interaction	Health	Viagra (Sildenafil)	PS				
Other		Professional	Cocaine (Cocaine)	SS				
			Cannabis (Cannabis)	SS				

Date:01/07/05ISR Number: 4550158-9Report Type:Expedited (15-DaCompany Report #KII-2004-0014482 Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Agitation	Study	Oxycodone					
Initial or Prolonged	Coma	Health	Hydrochloride					
Other	Multiple Drug Overdose	Professional	(Similar To Nda					
	Polysubstance Abuse	Other	20-553) (Oxycodone					
	Somnolence		Hydrochloride)	PS		ORAL	SEE TEXT,	
						ORAL		
			Morphine Sulfate					
			(Similar To Nda					
			19-516) (Morphine					
			Sulfate)	SS		ORAL	SEE TEXT,	
						ORAL		
			Cocaine (Cocaine)	SS		RESPIRATORY		
						(INHALATION)	SEE TEXT,	
						INHALATION		
			Ethanol (Ethanol)	SS		ORAL	SEE TEXT,	
						ORAL		
			Valium (Diazepam)	SS		ORAL	SEE TEXT,	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Marijuana (Cannabis) SS                      RESPIRATORY  
 Unknown                      C                      (INHALATION) INHALATION

Date:01/12/05ISR Number: 4549942-7Report Type:Expedited (15-DaCompany Report #PHBS2005NZ00543                      Age:43 YR    Gender:Male    I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anxiety Drug Abuser Drug Level Decreased Social Problem	Health Professional	Leponex Leponex	PS SS	Novartis Sector: Pharma Novartis Sector: Pharma	ORAL	300 mg/d	
			Leponex	SS	Novartis Sector: Pharma	ORAL	325 mg/d	
			Leponex	SS	Novartis Sector: Pharma	ORAL	350 mg/d	4320 MIN
			Leponex	SS	Novartis Sector: Pharma	ORAL	375 mg/d	2880 MIN
			Leponex	SS	Novartis Sector: Pharma	ORAL	400 mg/d	
			Marijuana	SS	UNKNOWN			
			Omeprazole	C	UNKNOWN		20 mg/d	
			Prednisolone	C	UNKNOWN		5 mg/d	
			Clonazepam	I	UNKNOWN			

Date:01/14/05ISR Number: 4556723-7Report Type:Expedited (15-DaCompany Report #2005002357                      Age:    Gender:Female    I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abnormal Behaviour Disturbance In Attention Drug Ineffective For Unapproved Indication Increased Appetite Medical Device Complication Memory Impairment Unevaluable Event Weight Increased	Consumer	Neurontin (Gabapentin)	PS		ORAL	1800 MG (300 MG, 1 IN 4 HR), ORAL	
			Cannabis (Cannabis)	SS		RESPIRATORY (INHALATION) INHALATION		
			Losartan Potassium (Losartan Potassium)	C				
			Pilocarpine Hydrochloride)	C				
			Levothyroxine Sodium (Levothyroxine Sodium)	C				
			Zolpidem Tartrate (Zolpidem Tartrate)	C				

Outcome PT  
 Hospitalization - Blood Amylase Increased  
 Initial or Prolonged Blood Creatinine  
 Other Increased  
 Blood Pressure Increased  
 Blood Urea Increased  
 Coma  
 Feeling Jittery  
 Heart Rate Increased  
 Hypoperfusion

21-Jul-2006 10:28 AM

Page: 170

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Outcome	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hypoxia							
Ischaemic Hepatitis							
Lethargy	Study	Oxycontin Tablets					
Lung Infiltration	Health	(Oxycodone					
Myocardial Infarction	Professional	Hydrochloride) Cr					
Pleural Effusion	Other	Tablet	PS		ORAL	ORAL	
Polysubstance Abuse		Benzodiazepine					
Respiratory Rate		Derivatives	SS		ORAL	ORAL	
Increased		Cannabis (Cannabis)	SS				
Rhabdomyolysis	Barbiturates	SS					
	Unknown	C					

Outcome	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Literature	Clonazepam Tablets					
	Health	Usp, 2 Mg (Purepac)	PS	Purepac	ORAL	PO	
Completed Suicide	Professional	Alprazolam Tablets					
Confusional State		Usp, 2 Mg (Purepac)	SS	Purepac	ORAL	PO	
Multiple Drug Overdose		Amitriptyline	SS		ORAL	PO	
Renal Failure Acute		Marijuana	SS		RESPIRATORY		
Rhabdomyolysis					(INHALATION)	INH	
Somnolence							
Tachycardia							

Outcome PT  
 Death Acidosis  
 Hospitalization - Aggression  
 Initial or Prolonged Alanine Aminotransferase  
 Increased  
 Aspartate

Aminotransferase  
 Increased  
 Aspiration  
 Blood Creatine  
 Phosphokinase Increased  
 Blood Creatinine  
 Increased  
 Bronchopneumonia  
 Cardiac Arrest  
 Coma  
 Completed Suicide  
 Convulsion  
 Drug Screen Positive  
 Electrocardiogram Qrs  
 Complex Prolonged  
 Electrocardiogram Qt  
 Prolonged  
 Electrolyte Imbalance  
 Glucose Urine Present  
 Haematuria  
 Haemodialysis  
 Haemorrhage  
 Heart Rate Decreased

21-Jul-2006 10:28 AM

Page: 171

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Adverse Event	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hyperglycaemia							
Hypotension							
Hypoxia	Literature	Clonidine					
Hypoxic Encephalopathy	Health	Hydrochloride					
International Normalised Ratio Increased	Professional	Tablets Usp, 0.3 Mg					
Multi-Organ Failure		(Purepac)	PS	Purepac	ORAL	PO	
Multiple Drug Overdose		Venlafaxine	SS		ORAL	PO	
Mydriasis		Mirtazapine	SS		ORAL	PO	
Myocardial Infarction		Marijuana	SS				
Papillary Muscle		Charcoal, Activated	SS				
Haemorrhage		Cocaine	SS				
Proteinuria		Amphetamine	C				
Prothrombin Time							
Prolonged							
Pupil Fixed							
Sinus Tachycardia							
Supraventricular							
Tachycardia							
Troponin Increased							
Ventricular Fibrillation							
Ventricular Tachycardia							
White Blood Cell Count							
Decreased							

Date:02/11/05ISR Number: 4583753-1Report Type:Expedited (15-DaCompany Report #2012272

Age:42 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Death	Consumer	Oxycontin Tablets					
Hospitalization - Initial or Prolonged	Accidental Overdose Asthenia	Health Professional	(Oxycodone Hydrochloride)	PS			SEE IMAGE	
Other Required	Back Pain Drug Abuser	Other	Diazepam (Diazepam) Oxazepam (Oxazepam)	SS SS				
Intervention to Prevent Permanent Impairment/Damage	Erectile Dysfunction Haematemesis Headache		Temazepam (Temazepam) Lorazepam (Lorazepam)		SS			
	Iron Deficiency Anaemia Mallory-Weiss Syndrome Tachycardia Tooth Disorder Tooth Extraction		Cannabnoids (Cannabis) Diphenhydramine Hydrochloride (Diphenhydramine Hydrochloride) Gabapentin (Gabapentin) Claritin (Loratadine) Zoloft (Sertraline Hydrochloride) Altace (Ramipril) Allopurinol (Allopurinol) Depakote (Valproate Semisodium) Soma (Carisoprodol) Relafen (Nabumetone)	SS SS C C C C C C C C				

21-Jul-2006 10:28 AM

Page: 172

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/14/05ISR Number: 4581970-8Report Type:Expedited (15-DaCompany Report #DE-ABBOTT-05P-062-0290030-00

Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Dependence Fatigue		Akineton Tabletten Ergenyl	PS SS		ORAL ORAL		
	Multiple Drug Overdose Intentional Suicide Attempt		Risperidone Hashish	SS SS		ORAL		

Date:02/16/05ISR Number: 4589272-0Report Type:Expedited (15-DaCompany Report #USA-2002-0002836

Age:45 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization -	Alcohol Withdrawal Syndrome	Consumer Health	Oxycontin (Oxycodone					



Cardiac Disorder Health Buprenorphine(Buprenorphine) SS  
 Drug Dependence Professional orphine) SS  
 Drug Interaction Other Cocaine (Cocaine) SS OVERDOSE  
 Fibrosis Cannabis(Cannabis,  
 Inflammation Cannabis Sativa) SS  
 Overdose  
 Renal Vessel Disorder

Date:02/23/05ISR Number: 4594071-XReport Type:Expedited (15-DaCompany Report #USA-2003-0009433 Age:42 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anxiety Back Pain	Consumer Health	Oxycontin Tablets (Oxycodone Hydrochloride)Cr					
Other	Cold Sweat Confusional State Delusion	Professional Other	Tablet PS			ORAL ORAL	20 MG, BID,	
	Depressed Mood		Alcohol (Ethanol)	SS				
	Disturbance In Attention		Marijuana (Annabis)	SS				
	Drug Dependence		Cocaine (Cocaine)	SS				
	Drug Ineffective	Narco	C					
	Drug Withdrawal Syndrome		Xanax(Alprazolam)	C				
	Feeling Abnormal							
	Hallucination, Auditory							
	Insomnia							
	Major Depression							
	Memory Impairment							
	Muscle Twitching							
	Pain							
	Paranoia							
	Polysubstance Abuse							
	Psychotic Disorder							
	Schizophrenia, Paranoid							
	Type							
	Tremor							
	Weight Decreased							
	Weight Increased							

Date:02/24/05ISR Number: 4603540-5Report Type:Periodic Company Report #041107-0000479 Age:44 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Intentional Drug Misuse	Literature	Methamphetamine Hcl					
		Health Professional Other	(Methamphetamine Hcl) PS Cocaine (Cocaine)	SS		ORAL PO RESPIRATORY (INHALATION) INH		
			Marijuana (Cannabis)	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/24/05ISR Number: 4603542-9Report Type:Periodic Company Report #041107-0000481 Age:30 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Suicide Attempt	Literature	Methamphetamine Hcl					
		Health Professional Other	(Methamphetamine Hcl) PS					
			Amitriptyline (Amitriptyline) SS		ORAL	PO		
			Cocaine (Cocaine) SS					

Date:03/02/05ISR Number: 4596404-7Report Type:Expedited (15-DaCompany Report #GB-JNJFOC-20050205883 Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Exposure During Pregnancy		Ibuprofen	PS				
	Drug Level Below Therapeutic	Subutex	SS			SUBLINGUAL		
	Multiple Drug Overdose	Diazepam	SS			OROPHARINGEAL		
		Oxazepam	SS					
		Cocaine	SS			intermittentl		
		Cannabinoids	SS		y			

Date:03/04/05ISR Number: 4601245-8Report Type:Expedited (15-DaCompany Report #KII-2005-0015351 Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Anoxic Encephalopathy Blood Cannabinoids Blood Pressure Decreased Coma Contusion Convulsion Drug Screen Positive Heart Rate Increased Metabolic Acidosis Opiates Polysubstance Abuse Rhabdomyolysis	Study Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-553)(Oxycodone Hydrochloride) PS Ssri Benzodiazepine Derivatives Naloxone(Naloxone) SS Tetrahydrocannabinol (Tetrahydrocannabimol) SS			ORAL ORAL ORAL ORAL ORAL ORAL		

Date:03/04/05ISR Number: 4601248-3Report Type:Expedited (15-DaCompany Report #KII-2005-0015322 Age:19 YR Gender:Male I/FU:I

Outcome	PT
Death	Anoxic Encephalopathy
Life-Threatening	Anuria
Hospitalization - Initial or Prolonged Other	Areflexia Blood Creatine Phosphokinase Abnormal Blood Creatine



Phosphokinase Increased  
 Blood Creatinine Abnormal  
 Blood Ph Decreased  
 Blood Potassium Decreased  
 Body Temperature  
 Decreased  
 Cardio-Respiratory Arrest  
 Coma  
 Corneal Reflex Decreased

21-Jul-2006 10:28 AM

Page: 175

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Dialysis								
Hypertension								
Liver Function Test Abnormal		Study	Oxycontin Tablets					
Polysubstance Abuse		Health	(Oxycodone					
Pupil Fixed		Professional	Hydrochloride) Cr					
Sinus Tachycardia		Other	Tablet	PS				
			Methadone(Methadone)	SS				
			Cocaine(Cocaine)	SS				
			Fentanyl(Fentanyl)	SS				
			Benzodiazepine					
			Derivatives	SS				
			Tetrahydrocannabinol					
			(Tetrahydrocannabinol)	SS				

Date:03/14/05ISR Number: 4610424-5Report Type:Expedited (15-DaCompany Report #USA-2003-0006203 Age:36 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain	Upper Consumer	Oxycontin Tablets					
Other	Alcoholism	Health	(Oxycodone					
	Anxiety	Professional	Hydrochloride) Cr					
	Arthralgia	Other	Tablet	PS		INTRAVENOUS		INTRAVENOUS
	Depression		Demerol (Pethidine					
	Drug Abuser		Hydrochloride)	SS		INTRAVENOUS		INTRAVENOUS
	Drug Dependence		Dilaudid					
	Drug Screen Positive		(Hydromorphone					
	Drug Withdrawal Syndrome		Hydrochloride)	SS		INTRAVENOUS		INTRAVENOUS
	Emotional Distress		Cocaine (Cocaine)	SS				
	Gastritis		Alcohol (Ethanol)	SS		ORAL	12, DAILY,	
	Headache					ORAL		
	Injury		Marijuana (Cannabis)	SS				
	Insomnia		Percodan					
	Mental Disorder		(Phenacetin,					
	Nausea		Homatropine					
	Pain		Terephthalate,					
	Polysubstance Dependence		Oxycodone	SS				
	Sickle Cell Anaemia With Crisis		Humulin (Insulin					
			Isophane, Human					

Vomiting

Biosynthetic,  
 Insulin Human) C  
 Folic Acid (Folic  
 Acid) C  
 Zoloft (Sertraline  
 Hydrochloride) C  
 Hydrochlorothiazide  
 (Hydrochlorothiazide  
 ) C  
 Paxil (Paroxetine  
 Hydrochloride) C  
 Restoril (Temazepam) C  
 Vitamin E  
 (Tocopherol) C  
 Prevacid  
 (Lansoprazole) C  
 Celebrex (Celecoxib) C  
 Zantac (Ranitidine  
 Hydrochloride) C

21-Jul-2006 10:28 AM

Page: 176

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:03/15/05ISR Number: 4610467-1Report Type:Expedited (15-DaCompany Report #KII-2005-0015431 Age:36 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Diastolic Increased	Study Health Professional	Oxycodone Hydrochloride (Similar To Nda 20-553) (Oxycodone Hydrochloride)	PS		ORAL	ORAL	
	Drug Abuser Fall	Other	Acetaminophen W/Oxycodone/Paraceta mol, Oxycodone Hydrochloride)	SS	ORAL	ORAL		
	Heart Rate Increased		Carisoprodol (Carisoprodol)	SS	ORAL	ORAL		
	Multiple Drug Overdose		Ethanol (Ethanol)	SS	ORAL	ORAL		
	Skin Laceration		Benzodiazepine Derivatives	SS				
			Marijuana (Cannabis)	SS				

Date:03/28/05ISR Number: 4619944-0Report Type:Expedited (15-DaCompany Report #DE-ABBOTT-05P-062-0290030-00 Age:24 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Fatigue Suicide Attempt		Akineton Tabletten Ergenyl	PS SS		ORAL ORAL		
	Unevaluable Event		Risperidone	SS		ORAL		
		Hashish	SS					

Date:04/05/05ISR Number: 4627495-2Report Type:Expedited (15-DaCompany Report #USA-2004-0018113

Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Death	Consumer	Oxycontin Tablets					
Other	Anoxic Encephalopathy	Health	(Oxycodone					
	Cardiac Arrest	Professional	Hydrochloride)Cr					
	Foreign Body Aspiration	Other	Tablet	PS				
	General Physical Health		Alcohol (Ethanol)	SS				
	Deterioration		Alprazolam					
	Multiple Drug Overdose		(Alprazolam)	SS				
	Accidental		Oxymorphone					
	Polysubstance Abuse		(Oxymorphone)	SS				
	Respiratory Arrest		Lidocaine					
			(Lidocaine)	SS				
			Cocaine (Cocaine)	SS				
			Cannabinoids	SS				

Date:04/05/05ISR Number: 4627591-XReport Type:Expedited (15-DaCompany Report #KII-2005-0015595

Age:18 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Calcium Decreased	Study	Oxycontin Tablets					
Initial or Prolonged	Crying	Health	(Oxycodone					
Other	Intentional Drug Misuse	Professional	Hydrochloride) Cr					
	Multiple Drug Overdose	Other	Tablet	PS		RESPIRATORY		
	Intentional					(INHALATION)	SEE IMAGE	
	Polysubstance Abuse		Acetaminophen					
	Suicidal Ideation		(Paracetamol)	SS		ORAL	SEE TEXT	
	Tachycardia		Marijuana (Cannabis)	SS		RESPIRATORY		

21-Jul-2006 10:28 AM

Page: 177

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

(INHALATION) INHALATION

Cocaine (Cocaine)	SS
Asa (Acetylsalicylic Acid)	SS

Date:04/08/05ISR Number: 4633397-8Report Type:Expedited (15-DaCompany Report #USA-2002-0002836

Age:45 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Alcohol Withdrawal	Consumer	Oxycontin Tablets 20					
Hospitalization -	Syndrom	Health	Mg(Oxycodone					
Initial or Prolonged	Anxiety	Professional	Hydrochloride) Cr					
Other	Arthralgia	Other	Tablet	PS		ORAL	20 MG, BID,	
	Completed Suicide					ORAL		
	Depression		Lorcet (Paracetamol,					
	Drug Abuser		Hydrocodone					
	Drug Dependence		Bitartrate) Unknown	SS		ORAL	10 MG, SEE	
	Drug Ineffective					TEXT, ORAL		
	Drug Withdrawal Syndrome		Marijuana (Cannabis)	SS		ORAL	40 MG, SEE	

Gun Shot Wound				TEXT, ORAL
Hypoaesthesia	Remeron			
Impaired Driving Ability	(Mirtazapine)	C		
Inadequate Analgesia	Relafen (Nabumetone)	C		
Loss Of Consciousness	Neurontin			
Muscle Spasms	(Gabapentin)	C		
Musculoskeletal Stiffness	Ultram	C		
Pain	Soma (Carisoprodol)	C		
Pain In Extremity	Effexor (Venlafaxine			
Paraesthesia	Hydrochloride)	C		
Polysubstance Abuse	Biaxin			
Suicidal Ideation	(Clarithromycin)	C		
Temperature Intolerance	Xanax (Alprazolam)	C		
Upper Respiratory Tract	Zanaflex (Tizanidine			
Infection	Hydrochloride)	C		
Weight Decreased	Tranxene			
	(Clorazepate			
	Dipotassium)	C		
	Zoloft (Sertraline			
	Hydrochloride)	C		
	Dilantin (Phenytoin			
	Sodium)	C		

Date:04/12/05ISR Number: 4633469-8Report Type:Expedited (15-DaCompany Report #USA-2003-0008901

Age:45 YR Gender:Male I/FU:F

Outcome PT  
 Hospitalization - Anger  
 Initial or Prolonged Back Pain  
 Other Bronchitis Acute  
 Burning Sensation  
 Carpal Tunnel Syndrome  
 Depression Suicidal  
 Diabetic Neuropathy  
 Drug Abuser  
 Drug Dependence  
 Drug Withdrawal Syndrome  
 Inadequate Analgesia  
 Lethargy  
 Mechanical Complication  
 Of Implant

21-Jul-2006 10:28 AM

Page: 178

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Nasopharyngitis							
Pain							
Polysubstance Abuse	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Pseudarthrosis	Consumer	Oxycontin Tablets					
Radicular Pain	Health	(Oxycodone					
Self-Injurious Ideation	Professional	Hydrochloride) Cr					
Tremor	Other	Tablet	PS		ORAL		
		Percocet (Oxycodone					

Hydrochloride,  
Paracetamol) SS ORAL 5 MG, HS,  
ORAL

Lortab (Paracetamol,  
Hydrochloride  
Bitartrate) SS  
Marijuana (Cannabis) SS  
Restoril (Temazepam) C  
Trazodone  
(Trazodone) C  
Phenobarbital  
(Phenobarbital) C  
Glyburide  
(Glibenclamide) C  
Ativan (Lorazepam) C  
Effexor (Venlafaxine  
Hydrochloride) C  
Valium (Diazepam) C  
Ambien (Zolpidem  
Tartrate) C

Date:04/15/05ISR Number: 4636459-4Report Type:Expedited (15-DaCompany Report #FR-ROCHE-401122 Age:18 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hallucination Suicide Attempt		Roaccutane	PS	Roche	ORAL	128	DAY
			Lexomil	SS	Roche	ORAL		
		Cannabis	SS			RESPIRATORY (INHALATION)		

Date:04/18/05ISR Number: 4638115-5Report Type:Expedited (15-DaCompany Report #PHEH2005US04277 Age:42 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatinine Increased Laboratory Test Abnormal		Lamisil	PS	Novartis Sector: Pharma	ORAL	250 mg, QD	91 DAY
			Marijuana	SS				
		Lamisil	SS		Novartis Sector: Pharma	ORAL	250 mg, QD	
		Celexa	C			ORAL	30 mg, QD	
		Neurontin	C			ORAL		

Date:04/19/05ISR Number: 4639106-0Report Type:Expedited (15-DaCompany Report #PHBS2004IT11483 Age:19 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Agitation Alanine Aminotransferase Increased Aspartate

21-Jul-2006 10:28 AM

Page: 179

Freedom Of Information (FOI) Report

Aminotransferase

Increased

Blood Cannabinoids

Blood Creatine

Report Source

Product

Role

Manufacturer

Route

Dose

Duration

Phosphokinase Increased

Clozapine

PS

Novartis Sector:

Blood Pressure Abnormal

Pharma

UNKNOWN

300 mg/d

730 DAY

Coma

Clozapine

SS

Novartis Sector:

Delirium

Pharma

UNKNOWN

1000 mg/d

Leukocytosis

Venlafaxine (Ngx)

SS

UNKNOWN

150 mg/d

730 DAY

Myoglobin Blood Increased

Venlafaxine (Ngx)

SS

UNKNOWN

900 mg/d

Neuroleptic Malignant

Cannabis

SS

Syndrome

Overdose

Pyrexia

Date:04/22/05ISR Number: 4644859-1Report Type:Expedited (15-DaCompany Report #KH-2005-0016010

Age:35 YR Gender:Male

I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Glucose Increased	Study	Morphine Sulfate					
Other	Lethargy	Health	(Similar To Nda					
	Loss Of Consciousness	Professional	19-516) (Morphine Sulfate) Unknown	PS		ORAL	ORAL	
	Overdose	Other	Ethanol (Ethanol)	SS		ORAL	ORAL	
	Oxygen Saturation Decreased		Cocaine (Cocaine)	SS		RESPIRATORY (INHALATION)	INHALATION	
	Polysubstance Abuse							
	Respiratory Rate Decreased		Marijuana (Cannabis)	SS				
	White Blood Cell Count Increased							

Date:04/28/05ISR Number: 4650264-4Report Type:Expedited (15-DaCompany Report #KII-2005-0016092

Age:20 YR Gender:Male

I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Glucose Increased	Study	Oxycodone Hydrochloride					
Other	Body Temperature Increased	Health	(Oxycodone Hydrochloride)	PS		ORAL	SEE TEXT,	
	Coma	Other				ORAL		
	Drug Abuser		Benzodiazepine Derivatives ()	SS		ORAL	ORAL	
	Pneumonia Aspiration		Cannabinoids ()	SS				
	Troponin Increased							
	Vomiting							

Date:05/02/05ISR Number: 4649538-2Report Type:Expedited (15-DaCompany Report #PHBS2005NZ06106

Age:23 YR Gender:Male

I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Pneumothorax		Clozaril	PS	Novartis Sector:			
				Pharma		ORAL	300 mg/d	
		Marijuana	SS					

Outcome  
Hospitalization -  
Initial or Prolonged

21-Jul-2006 10:28 AM

Page: 180

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Other

PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Alcohol Use	Study	Oxycontin Tablets					
Apnoea	Health	(Oxycodone					
Blood Glucose Increased	Professional	Hydrochloride ) Cr					
Blood Ph Decreased	Other	Tablet	PS		ORAL	ORAL	
Blood Pressure Decreased		Acetaminophen					
Coma		W/Oxycodone					
Drug Abuser		(Paracetamol,					
Electrocardiogram Qrs		Oxycodone					
Complex Prolonged		Hydrochloride)	SS		ORAL	ORAL	
Electrocardiogram Qt		Aspirin With					
Corrected Interval		Carisoprodol ( )	SS		ORAL	ORAL	
Prolonged		Diphenhydramine					
Loss Of Consciousness		(Diphenhydramine)	SS		ORAL	ORAL	
Multiple Drug Overdose		Antipsychotics()	SS		ORAL	ORAL	
Somnolence		Alcohol (Ethanol)	SS				
		Marijuana (Cannabis)	SS				

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abnormal Behaviour	Health	Oxycontin Tablets					
Other	Accidental Death	Professional	(Oxycodone					
	Accidental Overdose	Other	Hydrochloride) Cr					
	Apnoea		Tablet	PS		MG		
	Blood Cannabinoids		Alprazolam					
	Increased		(Alprazolam)	SS		MG		
	Bradycardia		Canabinoids					
	Bronchopneumonia		(Cannabinoids)	SS				
	Cardiac Arrest		Nortriptyline					
	Coma		(Nortriptyline)	SS				
	Confusional State							
	Drug Toxicity							
	Dysarthria							
	Lethargy							
	Myocardial Infarction							
	Psychomotor Retardation							
	Pulmonary Oedema							
	Pulse Absent							
	Pulse Pressure Decreased							

Respiration Abnormal  
 Self Injurious Behaviour  
 Urine Cannabinoids  
 Increased

Date:05/09/05ISR Number: 4658698-9Report Type:Expedited (15-DaCompany Report #DSA\_26341\_2005 Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bowel Sounds Abnormal Coma	Foreign Health Professional Other	Tavor Cannabis	PS SS		ORAL	DF ONCE PO DF ONCE	

21-Jul-2006 10:28 AM

Page: 181

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:05/10/05ISR Number: 4657838-5Report Type:Expedited (15-DaCompany Report #PHEH2005US04277 Age:42 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Cannabinoids Increased Blood Creatinine Increased Laboratory Test Abnormal		Lamisil Pharma Marijuana Lamisil SS Novartis Sector: Pharma	PS SS Novartis Sector: Pharma	Novartis Sector: ORAL	ORAL	250 mg, QD 250 mg, QD 30 mg, QD	91 DAY

Date:05/12/05ISR Number: 4662023-7Report Type:Expedited (15-DaCompany Report #2005067566 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alcohol Use Asthenia Drug Dependence Heart Rate Increased	Consumer (Diphenhydramine)	Benadryl (Diphenhydramine)	PS		ORAL	2 TABS BID,	
			Ethanol (Ethanol) Cannabis (Cannabis0	SS SS		ORAL RESPIRATORY (INHALATION)	ORAL ORAL	

Date:05/16/05ISR Number: 4663732-6Report Type:Expedited (15-DaCompany Report #USA-2005-0020175 Age:18 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Homicide Intentional Drug Misuse Polysubstance Abuse	Consumer Other	Oxycontin Tablets(Oxycodone Hydrochloride) Cr	PS				
		Tablet Alcohol (Ethanol)	PS SS					



Marijuana (Cannabis) SS

Date:05/19/05ISR Number: 4666065-7Report Type:Expedited (15-DaCompany Report #PHEH2005US04277

Age:42 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Cannabinoids		Lamisil	PS	Novartis Sector:			
	Increased			Pharma	ORAL	250 mg, QD	91 DAY	
	Blood Creatinine		Marijuana	SS				
	Increased		Lamisil	SS	Novartis Sector:			
	Laboratory Test Abnormal			Pharma	ORAL	250 mg, QD		
		Celexa	C		ORAL	30 mg, QD		
		Neurontin	C		ORAL			

Date:05/23/05ISR Number: 4672934-4Report Type:Expedited (15-DaCompany Report #USA-2003-0009433

Age:42 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization -	Alcoholism
Initial or Prolonged	Anxiety
Other	Back Pain
	Cervicobrachial Syndrome
	Cold Sweat
	Confusional State
	Delusion
	Depressed Mood

21-Jul-2006 10:28 AM

Page: 182

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Depression	Disturbance In Attention	Drug Abuser	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
		Drug Dependence	Consumer	Oxycontin					
		Drug Ineffective	Health	Tablets(Oxycodone					
		Drug Withdrawal Syndrome	Professional	Hydrochloride) Cr					
		Hallucination, Auditory	Other	Tablet	PS		ORAL	20 MG, BID,	
		Insomnia					ORAL; 20 M G,		
		Major Depression					TID		
		Malaise		Alcohol (Ethanol)	SS				
		Memory Impairment		Marijuana(Cannabis)	SS				
		Muscle Spasms		Cocaine(Cocaine)	SS				
		Muscle Twitching		Vicodin(Paracetamol,					
		Pain		Hydrocodone					
		Paranoia		Bitartrate) Tablet	SS				
		Psychotic Disorder		Norco	C				
		Schizophrenia, Paranoid		Xanax (Alprazolam)	C				
		Type							
		Tremor							
		Weight Decreased							
		Weight Increased							

Outcome PT  
 Death Abnormal Behaviour  
 Hospitalization - Alcoholism  
 Initial or Prolonged Anxiety  
 Other Arthralgia  
 Asthenia  
 Bone Pain  
 Borderline Mental  
 Impairment  
 Bronchitis  
 Cardiomegaly  
 Chronic Obstructive  
 Pulmonary Disease  
 Delinquency  
 Delirium  
 Depressed Level Of  
 Consciousness  
 Diarrhoea  
 Drug Abuser  
 Drug Dependence  
 Drug Toxicity  
 Drug Withdrawal Syndrome  
 Dyspepsia  
 Emotional Distress  
 Fall  
 Generalised Anxiety  
 Disorder  
 Hand Fracture  
 Hypertension  
 Hypoaesthesia  
 Inadequate Analgesia  
 Learning Disability  
 Major Depression  
 Male Sexual Dysfunction  
 Musculoskeletal Stiffness

21-Jul-2006 10:28 AM

Page: 183

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Nocturia							
Obesity							
Overdose	Consumer	Oxycontin Tablets 20					
Pain In Extremity	Health	Mg (Oxycodone					
Paraesthesia	Professional	Hydrochloride)Cr					
Pneumoconiosis	Other	Tablet	PS		ORAL	20 MG, ORAL	
Pollakiuria		Oxycontin Tabetls 40					
Pyrexia		Mg(Oxycodone					
Somnolence		Hydrochloride)Cr					
Speech Disorder		Tablet	SS		ORAL	40 MG, ORAL	
Spinal Osteoarthritis							

Suicidal Ideation  
Tooth Extraction  
Urinary Incontinence  
Vomiting

Hydrocodone/Apap  
(Paracetamol,  
Hydrocodone  
Bitartrate) SS

ORAL 10 MG, SEE  
TEXT, ORAL

Amitripyline  
(Amitriptyline) SS  
Acetaminophen  
(Paracetamol) SS  
Cannabinoids SS  
Tylox (Oxycodone  
Terephthalate) C  
Ativan (Lorazepam) C  
Xanax (Alprazolam) C  
Vioxx (Rofecoxib) C  
Pamelor  
(Nortriptyline  
Hydrochloride) C  
Ultram C  
Skelaxin  
(Metaxalone) C  
Buspar (Buspirone  
Hydrochloride) C  
Tenormin (Atenolol) C  
Narcan C  
Ambien (Zolpidem  
Tartrate) C  
Haldol (Haloperidol) C  
Cogentin  
(Benzatropine  
Mesilate) C  
Narcan C  
Diazepam (Diazepam) C  
Baclofen (Baclofen) C  
Lorcet C  
Toradol (Ketorolac  
Tromethamine) C  
Phenergan  
(Promethazine  
Hydrochloride) C  
E-Mycin  
(Erythromycin) C  
Flovent (Fluticasone  
Propionate) C  
Theo-Dur C  
Prednisone  
(Prednisone) C  
Soma (Carisoprodol) C  
Proventil Inhaler  
(Salutamol) C

100 MG, NOCTE

Percocet Tablet C  
Penicillin V-K  
(Phenoxymethylpenicillin Potassium)  
Tablet C

Date:05/26/05ISR Number: 4677258-7Report Type:Expedited (15-DaCompany Report #DSA\_26341\_2005 Age:43 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bowel Sounds Abnormal Intentional Drug Misuse Overdose Somnolence	Foreign Health Professional Other	Tavor Cannabis	PS SS		ORAL PO	10 TAB ONCE	

Date:05/27/05ISR Number: 4678273-XReport Type:Expedited (15-DaCompany Report #KII-2005-0016729 Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Loss Of Consciousness Multiple Drug Overdose Polysubstance Abuse	Health Professional Other	Oxycontin Tablets (Oxydone Hydrochloride) Cr					
		Tablet	PS	ORAL		ORAL		
		Hydromorphone Hcl (Similar To Nda 21-044)(Hydromorphone Hydrochloride) Gamma	SS	ORAL		ORAL		
		Hydroxybutyrate And Analog Barbiturates Benzodiazepine Derivatives Marijuana (Cannabis) Cocaine (Cocaine)	SS SS SS SS SS	ORAL		ORAL		

Date:06/06/05ISR Number: 4687021-9Report Type:Expedited (15-DaCompany Report #2003186135FR Age:35 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest Drug Abuser Drug Toxicity Multi-Organ Failure	Foreign Health Professional	Xanax Tablet (Alprazolam) Methadone (Methadone) Nordaz (Nordazepam) Cannabis (Cannabis)	PS SS SS		ORAL ORAL	(0.25 MG), (5 MG), ORAL (7.5 MG),	

Date:06/13/05ISR Number: 4690867-4Report Type:Expedited (15-DaCompany Report #USA-2003-0009433 Age:42 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization -	Back Pain

Initial or Prolonged Cervicobrachial Syndrome  
 Other Cold Sweat  
 Delusion

21-Jul-2006 10:28 AM

Page: 185

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Depressed Mood  
 Disturbance In Attention  
 Drug Abuser  
 Drug Dependence  
 Drug Ineffective  
 Drug Withdrawal Syndrome  
 Feeling Abnormal  
 Hallucination, Auditory  
 Major Depression  
 Memory Impairment  
 Muscle Spasms  
 Muscle Twitching  
 Pain  
 Paranoia  
 Psychotic Disorder  
 Schizophrenia, Paranoid  
 Type  
 Suicide Attempt  
 Weight Decreased  
 Weight Increased

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Consumer	Oxycontin					
Health	Tablets(Oxycodone					
Professional	Hydrochloride) Cr					
Other	Tablet	PS		ORAL	SEE IMAGE	
	Alcohol (Ethanol)	SS				
	Marijuana (Cannabis)	SS				
	Cocaine (Cocaine)	SS				
	Vicodin					
	(Paracetamol,					
	Hydrocodone					
	Bitartrate)	C				
	Norco	C				
	Xanax (Alprazolam)	C				

Date:06/15/05ISR Number: 4690583-9Report Type:Expedited (15-DaCompany Report #FR-ROCHE-401122 Age:18 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hallucination Overdose		Lexomil	PS	Roche	ORAL		
			Procuta	SS		ORAL	128 DAY	
			Cannabis	SS		RESPIRATORY (INHALATION)		

Date:06/20/05ISR Number: 4696351-6Report Type:Expedited (15-DaCompany Report #KII-2005-0016996 Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anion Gap Increased	Study	Morphine Sulfate					
Hospitalization -	Blood Ph Decreased	Health	(Similar To Nda					
Initial or Prolonged	Blood Pressure Increased	Professional	19-516) (Morphine					
Other	Bowel Sounds Abnormal	Other	Sulfate)	PS		ORAL	ORAL	
	Brain Death		Xanax (Alprazolam)	SS		ORAL	ORAL	
	Brain Oedema		Marijuana (Cannabis)	SS				
	Coma		Cocaine (Cocaine)	SS				
	Drug Screen Positive							
	Eye Rolling							
	Flushing							
	Hypotension							

Hypoxia  
 Ischaemia  
 Miosis  
 Nystagmus  
 Polysubstance Abuse  
 Pupillary Reflex Impaired  
 Respiratory Arrest  
 Sinus Tachycardia  
 Thermal Burn

21-Jul-2006 10:28 AM

Page: 186

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/20/05ISR Number: 4696410-8Report Type:Expedited (15-DaCompany Report #KII-2005-0017040 Age:38 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Aggression Agitation Confusional State Depressed Level Of Consciousness Drug Abuser Drug Screen Positive Dyskinesia Respiratory Rate Increased Staring Tremor	Study Health Professional Other	Oxycontin Tablets (Oxycodone Hydrochloride)Cr Tablet Oxycodone Hydrochloride (Similar To Nda 20-553) (Oxycodone Hydrochloride) Acetaminophen W/Hydrocodone Bitartrate(Paracetam ol, Hydrocodone Bitartrate) Muscle Relaxants() Benzodiazepine Derivatives() Cannabis(Cannabis)	PS		ORAL	ORAL	
						ORAL	ORAL	
						ORAL	ORAL	
						ORAL	ORAL	
						ORAL	ORAL	
						ORAL	ORAL	
						ORAL	ORAL	
						ORAL	ORAL	
						ORAL	ORAL	

Date:06/28/05ISR Number: 4703604-1Report Type:Expedited (15-DaCompany Report #KII-2005-0017062 Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Anoxic Encephalopathy Blood Creatinine Increased Blood Electrolytes Abnormal Cardiac Arrest Neurological Examination Abnormal Polysubstance Abuse	Study Health Professional Other	Morphine Sulfate (Similar To Nda 19-516) (Morphine Sulfate) Unknown Methadone (Methadone) Cocaine (Cocaine) Marijuana (Cannabis) Antiepileptics()	PS SS SS SS				

Rhabdomyolysis  
 Toxicologic Test Abnormal  
 Troponin Increased  
 Urine Output Decreased

Benzodiazepine  
 Derivatives() SS  
 Ssri() SS

Date:06/28/05ISR Number: 4704430-XReport Type:Expedited (15-DaCompany Report #CAN-2005-0000284 Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Foreign	Oxycontin Tablets					
Other	Hepatitis B	Consumer	(Oxycodone					
	Hepatitis C	Other	Hydrochloride) Cr					
	Intentional Drug Misuse		Tablet	PS		ORAL	SEE TEXT,	
	Polysubstance Abuse					ORAL	SEE TEXT,	
		Marijuana (Cannabis)		SS				

Date:06/30/05ISR Number: 4706961-5Report Type:Expedited (15-DaCompany Report #2005-DE-02356GD Age: Gender:Unknown I/FU:I

Outcome PT  
 Death Acute Pulmonary Oedema  
 Drug Toxicity  
 Intentional Drug Misuse

21-Jul-2006 10:28 AM

Page: 187

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Overdose  
 Polysubstance Abuse

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Literature	Cocaine (Cocaine)	PS				
	Oxycodone					
	(Oxycodone)	SS				
	Meprobamate					
	(Meprobamate)	SS				
	Carisoprodol					
	(Carisoprodol)	SS				
	Marijuana (Cannabis					
	Sativa)	SS				

Date:06/30/05ISR Number: 4706993-7Report Type:Expedited (15-DaCompany Report #2005-DE-02356GD Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Acute Pulmonary Oedema	Literature	Cocaine (Cocaine)	PS				
	Drug Abuser		Oxycodone					
	Drug Interaction		(Oxycodone)	SS				
	Drug Toxicity		Meprobamate					
	Intentional Drug Misuse		(Meprobamate)	SS				
	Overdose		Carisoprodol					
			(Carisoprodol)	SS				

Marijuana (Cannabis  
Sativa) SS

21-Jul-2006 10:28 AM

Page: 188

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Summary report for FOI selections:

Selection by inexact search of active ingredient:



CANNABIS%

Selection by inexact search of Tradename/Verbatim:  
NOPROD%

Total number of reports: 513

From: 01-NOV-1997 To: 30-JUN-2005