

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/02/97ISR Number: 3003632-0Report Type:Expedited (15-DaCompany Report #USA/97/02799/LEX Age:16 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Arrhythmia	Consumer	Clozaril	PS		ORAL	2 TABLETS	
Initial or Prolonged	Dizziness		Marijuana	SS		2"JOINTS"		
Other	Drug Interaction							
	Fatigue							
	Loss Of Consciousness							
	Overdose							
	Stupor							

Date:12/12/97ISR Number: 3006939-6Report Type:Expedited (15-DaCompany Report #9713117 Age:18 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Creatine	Health	Zyrtec	PS			10.00 MG	
Initial or Prolonged	Phosphokinase Increased	Professional					TOTAL:DAILY	
Required	Confusional State	Other	Marijuana	SS				
Intervention to	Convulsion		Lysergic Acid					
Prevent Permanent	Disorientation		Diethylamide	C				
Impairment/Damage	Drug Withdrawal Syndrome		Serevent	C				
	Head Injury	Vanceril	C					
	Headache	Ventolin	C					
	Hypoglycaemia	Vancenase	C					
	Liver Function Test							
	Abnormal							
	Loss Of Consciousness							
	Nystagmus							
	Pharyngitis							
	Syncope							
	Tri-Iodothyronine							
	Increased							
	Vomiting							

Date:12/12/97ISR Number: 3006940-2Report Type:Expedited (15-DaCompany Report #9713117 Age:18 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Creatine	Health	Zyrtec	PS		UNKNOWN	10 MG TOTAL	
Initial or Prolonged	Phosphokinase Increased	Professional					DAILY	
	Clonic Convulsion	Other	Marijuana	SS			NOT SPECIFIED	
	Confusional State		Lysergic Acid					
	Convulsion		Diethylamide	C				
	Drug Abuser		Serevent	C				
	Hepatic Function Abnormal		Vanceril	C				
	Hypoglycaemia		Ventolin	C				

Vomiting

Date:12/29/97ISR Number: 3013519-5Report Type:Expedited (15-DaCompany Report #M058234

Age: Gender:Female I/FU:F

Outcome PT
Hospitalization - Alcohol Withdrawal
Initial or Prolonged Syndrome
Alcoholic Hangover

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	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Amnesia							
Chills							
Depression							
Diarrhoea	Stadol	PS				1 BOTTLE Q2D	
Dizziness					NASAL SP		
Drug Withdrawal Syndrome		Marijuana	SS			INH	
Dysphoria	Alcohol	SS		ORAL	PO		
Euphoric Mood	Percodan	SS		ORAL	PO		
Feeling Jittery	Hydrocodone	C					
Hepatic Function Abnormal		Promethazine	C				
Hypercholesterolaemia		Sumatriptan	C				
Hyperhidrosis							
Hypertriglyceridaemia							
Hyperventilation							
Lethargy							
Libido Decreased							
Liver Function Test Abnormal							
Loss Of Consciousness							
Personality Disorder							
Vomiting							

Date:12/29/97ISR Number: 3014101-6Report Type:Expedited (15-DaCompany Report #M074175

Age: Gender:Female I/FU:I

	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Outcome PT							
Hospitalization - Amnesia		Stadol	PS		NASAL	1 BOTTLE QD	
Initial or Prolonged Arthritis Allergic					NASAL SP		
Disability							
Bronchitis		Cocaine	SS				
Depression		Xanax	SS	ORAL		0.5 MG QID	
Drug Abuser					ORAL		
Drug Dependence		Marijuana	SS				
Nightmare		Propranolol	C				
Panic Attack		Axid	C				
Sedation		Lithobid	C				
Suicide Attempt		Butalbital	C				
	Pamelor	C					
	Altace	C					

Calan Sr C
 Lopid C
 Prozac C
 Doxycycline C
 Tofranil C
 Thorazine C
 Serzone C

Date:01/21/98ISR Number: 3019225-5Report Type:Expedited (15-DaCompany Report #98-01-0149 Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Delusion Hallucination Schizophrenia, Paranoid Type	Study Health Professional Study Other	Intron Blinded - Ribavirin SS	PS		SUBCUTANEOUS SUBCUTANEOUS ORAL ORAL	3 MU TIW 1200 MG/DAY	
			Marijuana Nph Insulin Buspar Olanzapine					SS C C C

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Date:01/29/98ISR Number: 3112226-8Report Type:Periodic Company Report #97USA10832 Age:15 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion	Consumer	Ritalin Marijuana	PS SS		ORAL RESPIRATORY (INHALATION) INHALATION	DAILY, ORAL	2 YR

Date:03/02/98ISR Number: 3128671-0Report Type:Periodic Company Report #9721904 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Paranoia	Consumer	Zoloft Marijuana	PS SS		ORAL RESPIRATORY (INHALATION) INHALATION	ORAL	

Date:03/02/98ISR Number: 3132876-2Report Type:Periodic Company Report #9700362 Age:19 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depersonalisation Drug Dependence	Consumer	Zoloft	PS		ORAL TOTAL:DAILY:O RAL INHALATION	50.00 MG	
		Marijuana	SS					

Date:03/02/98ISR Number: 3143570-6Report Type:Periodic Company Report #9704334 Age:21 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depression	Consumer	Zoloft Tablets	PS		ORAL	ORAL	
		Marijuana	SS			INHALATION		
		Alcohol	SS	ORAL		ORAL		
		Oral Contraceptives	C					
		Nicotine	C					

Date:03/06/98ISR Number: 3145888-XReport Type:Periodic Company Report #8-97016-001B Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Toxicologic Test	Abnormal Health	Effexor	PS		ORAL	37.5 MG.	
		Professional				TWICE DAILY		
		Company				ORAL		
		Representative	Marijuana	SS				
		Marijuana	C					

Date:03/17/98ISR Number: 3055729-7Report Type:Expedited (15-DaCompany Report #8-98065-002D Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion	Health	Effexor	PS		ORAL	6300 MG TOTAL	
	Loss Of Consciousness	Professional				DOSE	ORAL	
	Overdose	Company	Marijuana	SS				
		Representative						

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Freedom Of Information (FOI) Report

Date:04/24/98ISR Number: 3072865-XReport Type:Expedited (15-DaCompany Report #8-98065-002D Age:17 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion	Health	Effexor Xr	PS		ORAL	6300MG/TOTAL:	
	Drug Abuser	Professional				DOSE/ORAL		
	Loss Of Consciousness	Company	Marijuana	SS				
	Overdose	Representative						

Date:04/29/98ISR Number: 3071690-3Report Type:Expedited (15-DaCompany Report #8-98104-052N 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					ORAL		

Exposure To Therapeutic	Crack Cocaine	SS	2	WK
Drugs	Ethanol	SS	55	DAY
Congenital Anomaly	Marijuana	SS	2	WK
Limb Malformation	Antihistamine	C		
Small For Dates Baby	Crack Cocaine	C		
	Decongestants	C		
	Ethanol	C		
	Marijuana	C		

Date:05/04/98ISR Number: 3074164-9Report Type:Expedited (15-DaCompany Report #8-98104-050N Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Cleft Palate	Literature	Antabuse	PS		ORAL	250 MG DAILY	
	Clubbing					ORAL		
	Complications Of Maternal		Crack Cocaine	SS			2	WK
	Exposure To Therapeutic		Ethanol	SS		BINGE	74	DAY
	Drugs	Marijuana	SS			2	WK	
	Congenital Anomaly		Antihistamine	C				
	Limb Deformity		Decongestants					
	Small For Dates Baby		Intermittently	C				

Date:05/04/98ISR Number: 3074167-4Report Type:Expedited (15-DaCompany Report #8-98104-052N Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Cleft Palate	Literature	Antabuse	PS		ORAL	250 MG DAILY	
	Limb Reduction Defect					ORAL		
	Neonatal Complications Of		Crack Cocaine	SS			2	WK
	Substance Abuse		Ethanol	SS			74	DAY
	Small For Dates Baby		Marijuana	SS			2	WK
		Antihistamine	C					
		Decongestants	C					

Date:05/20/98ISR Number: 3167354-8Report Type:Periodic Company Report #8-98079-009D Age:17 YR Gender:Male I/FU:I

Outcome	PT
Other	Drug Interaction
	Emotional Disorder
	Hypertension
	Musculoskeletal Stiffness
	Pain

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Tachycardia

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
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Health Professional Effexor Xr PS ORAL 150 MG ONCE DAILY ORAL
 Marijuana SS
 Depakote C

Date:06/05/98ISR Number: 3174987-1Report Type:Periodic Company Report #80134 Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Laboratory Test Interference Toxicologic Test Abnormal	Health Professional	Accutane Capsules (Isotretinoin)	PS		ORAL 1.0 X PER DAY ORAL	40.0000 MG	
			Marijuana (Cannabis)	SS				

Date:07/15/98ISR Number: 3252393-9Report Type:Periodic Company Report #9814436 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Erectile Dysfunction	Consumer	Viagra Tablets	PS		ORAL	50.00 MG	
			Marijuana	SS		TOTAL; PRN; ORAL RESPIRATORY (INHALATION) INHALATION	25 YR	

Date:07/16/98ISR Number: 3105834-1Report Type:Expedited (15-DaCompany Report #1998-06-0833 Age:42 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression Agitation	Study Health	Intron A	PS		SUBCUTANEOUS	10-3 MU	
Other	Akathisia Anger Anxiety Depression Drug Abuser Hostility Mental Disorder	Professional Other	Ribavarin	SS		ORAL	600 MG BID	
			Marijuana	SS		ORAL	DAILY	
			Paxil	SS			20 MG DAILY	
			Zestril	C				
			Hydrochlorothiazide	C				
			Trazodone	C				

Date:08/27/98ISR Number: 3122628-1Report Type:Expedited (15-DaCompany Report #M072939 Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Decreased Appetite	Other	Stadol Nasal Spray	PS		NASAL	1 BOTTLE Q2D	
Disability	Depression		Demerol	SS		NASAL SP	5 YR	
	Drug Dependence		Lorcet	SS			3 YR	
	Drug Withdrawal Syndrome		Risperdal	SS			3 YR	
	Dysarthria		Marijuana	SS			3 YR	
	Insomnia		Alcohol	C				
	Weight Decreased		Valium	C				
			Xanax	C				

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Date:08/28/98ISR Number: 3122609-8Report Type:Expedited (15-DaCompany Report #1998-08-0644 Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Aggression	Study	Intron-A	PS		SUBCUTANEOUS	2 MU TIW	
		Health Professional Other	Ribavirin	SS		SUBCUTANEOUS ORAL	600 MG QD	
			Alcohol Marijuana	SS SS		UNKNOWN UNKNOWN		

Date:09/03/98ISR Number: 3125581-XReport Type:Expedited (15-DaCompany Report #8-98243-055A Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Drug Level Above Therapeutic	Health Professional	Serax Cocaine	PS SS				
	Electrocardiogram Qt Prolonged		Lithium	SS				
	Loss Of Consciousness		Marijuana Elavil	SS SS				
	Overdose		Librium	SS				

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 Professional	Dilantin (Phenytoin Sodium)	PS		ORAL	ORAL	
			Anti-Epileptic Medication (Unspecified)	SS				
			Marijuana (Cannabis)	SS		INHALATION		

Date:11/24/98ISR Number: 3162141-9Report Type:Direct Company Report # Age:22 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Cerebrovascular Accident		Amphetamine	PS				
Disability Required	Cognitive Disorder		Marijuana	SS				
Intervention to Prevent Permanent Impairment/Damage	Coma Convulsion							
	Drug Abuser							
	Liver Disorder							
	Muscle Injury							
	Myocardial Infarction							
	Occupational Physical							

Problem
Renal Impairment

Date:01/25/99ISR Number: 3185579-2Report Type:Expedited (15-DaCompany Report #JAUSA-35799

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

Outcome PT
Hospitalization - Abdominal Distension
Initial or Prolonged Akinesia
Bowel Sounds Abnormal
Cardiac Murmur
Complications Of Maternal

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Exposure To Therapeutic

Drugs

Cyanosis

Grand Mal Convulsion	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hyperreflexia	Health	Risperdal	PS	Janssen	ORAL	ORAL	
Neonatal Complications Of Substance Abuse	Professional	Cocaine	SS		ORAL	ORAL	
Pallor	Unspec.)	Marijuana (Opiate	SS				
Petechiae	Benzodiazepines	SS					
	Depakote	C					
	Zoloft	C					
	Ventolin	C					

Date:02/04/99ISR Number: 3300930-8Report Type:Periodic Company Report #M077924

Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Confusional State	Health	Professional	Serzone Tabs	PS		ORAL	ORAL	
		Professional	Marijuana	SS		ORAL	ORAL	

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					
Insomnia	Professional		(Methylphenidate					
Overdose			Hydrochloride)	PS		ORAL	DAILY, ORAL	
Psychotic Disorder			Marijuana (Cannabis)	SS		RESPIRATORY		
				(INHALATION)		INHALATION		
			Wellbutrin Tablet					
			(Amfebutamone					
			Hydrochloride)	SS		ORAL	ORAL	

Date:02/04/99ISR Number: 3407550-5Report Type:Periodic Company Report #98USA10537 Age:18 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abnormal Behaviour Drug Interaction Irritability	Health	Ritalin Tablet 10 Mg	PS				
		Professional	(Methylphenidate Hydrochloride)	PS		ORAL	10 MG, QD,	
						ORAL		
			Ritalin-Sr Slow Release Tablet 20 Mg					
			(Methylphenidate Hydrochloride)	SS		ORAL	20 MG, DAILY,	
						ORAL		
			Marijuana Unknown (Cannabis)	SS				INHALATION

Date:02/25/99ISR Number: 3207783-7Report Type:Periodic Company Report #9704334 Age:21 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depression	Consumer	Zoloft Tablets	PS		ORAL		
		Marijuana	SS			RESPIRATORY (INHALATION)		
			Alcohol	SS		ORAL		
			Oral Contraceptives	C				

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Nicotine C

Date:02/25/99ISR Number: 3211929-4Report Type:Periodic Company Report #9804561 Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser Drug Interaction	Consumer	Zoloft Tablets	PS		ORAL	100.00 MG	
		Health					TOTAL:DAILY:O	
		Professional					RAL	
			Ritalin	SS		ORAL	40.00 MG	
							TOTAL:DAILY:O	
							RAL	
			Marijuana	SS				

Date:02/25/99ISR Number: 3217080-1Report Type:Periodic Company Report #9812051 Age:17 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction Malaise Muscle Twitching	Health	Zoloft Tablets	PS		ORAL	50 MG TOTAL	
		Professional					DAILY ORAL	
			Marijuana	SS		RESPIRATORY (INHALATION)		INHALATION

Oral Contraceptive C

Date:02/25/99ISR Number: 3217523-3Report Type:Periodic Company Report #9803009 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction Psychotic Disorder	Health Professional Company Representative	Zoloft Tablets Marijuana	PS SS		ORAL	ORAL	

Date:02/25/99ISR Number: 3217525-7Report Type:Periodic Company Report #9803010 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction Psychotic Disorder	Health Professional Company Representative	Zoloft Tablets Marijuana	PS SS		ORAL	ORAL	

Date:03/17/99ISR Number: 3221445-1Report Type:Direct Company Report # Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Agitation Irritability Lethargy Sedation Tachycardia	Revirarant Marijuana	PS SS					

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Date:03/30/99ISR Number: 3230085-XReport Type:Expedited (15-DaCompany Report #9911866 Age:29 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Abdominal Pain	Upper Consumer	Zoloft Tablets	PS		ORAL	ORAL	
Intervention to	Drug Interaction		Wellbutrin	SS				
Prevent Permanent	Flatulence		Marijuana	SS				
Impairment/Damage			Beer	SS				

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 Drug Abuser	Literature Health Professional	Ultram (50 Mg Tablet) (Tramadol Hydrochloride)	PS		ORAL		
		Marijuana (Cannabis) Benzodiazepine	SS		ORAL	ORAL		

Date:07/07/99ISR Number: 3298598-2Report Type:Expedited (15-DaCompany Report #9927776

Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Electrocardiogram Qt	Foreign	Zoloft Tablets	PS		ORAL	100.00 MG	
Intervention to	Prolonged	Health				TOTAL:ORAL		
Prevent Permanent Impairment/Damage		Professional	Marijuana	SS				

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, With Postpartum Onset	Consumer	Zoloft Tablets	PS		ORAL	100.00 MG	
Intervention to						TOTAL:DAILY:O		
Prevent Permanent Impairment/Damage	Depression Dizziness		Alcohol	SS		RAL		
	Drug Level Above Therapeutic		Marijuana	SS				
	Feeling Abnormal		Ibuprofen	C				
	III-Defined Disorder Mental Disorder Road Traffic Accident							

Date:08/30/99ISR Number: 3337323-3Report Type:Expedited (15-DaCompany Report #9932145

Age:28 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Balance Disorder	Consumer	Zoloft Tablets	PS		ORAL	100.00 MG	
Intervention to	Brief Psychotic Disorder, With Postpartum Onset	Health				TOTAL DAILY		
Prevent Permanent Impairment/Damage	Depression	Professional	Alcohol	SS		ORAL		
	Dizziness		Marijuana	SS				
	Feeling Abnormal		Ibuprofen	C				
	Headache							
	III-Defined Disorder Mental Impairment Road Traffic Accident							

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

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Distension 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 Pallor Pco2 Decreased Petechiae Ventricular Septal Defect	Health Professional	Risperdal(Tablet) (Risperidone) Cocaine(Cocaine) Marijuana(Opiat) Unspecified (Benzodiazepine Derivatives) Depakote C Zolof C Ventolin C	PS SS SS		ORAL ORAL NASAL ORAL	ORAL ORAL INHALA ORAL	

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 Drug Interaction Grand Mal Convulsion	Health Professional	Lamisil (Terbinafine Hydrochloride) Marijuana (Cannabis) Dilantin C	PS SS		ORAL A DAY, ORAL 1 CIGARETTE, INHALATION 1 DAY	250 MG, ONCE	

Date:01/18/00ISR Number: 3445028-3Report Type:Expedited (15-DaCompany Report #S00-USA-00019-01

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Confusional State Drug Effect Decreased Drug Hypersensitivity Fatigue Hallucination Insomnia Memory Impairment Nervousness Paranoia Psychomotor Hyperactivity Sedation	Health Professional	Flumadine (Rimantadine Hydrochloride) Marijuana (Marijuana) Claritin-D C	PS SS C		ORAL	100 MG BID PO	

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Date:01/27/00ISR Number: 3447738-0Report Type:Periodic Company Report #9953044 Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dry Skin Face Oedema Pruritus	Consumer	Viagra Tablets	PS		ORAL	50.00 MG	
						TOTAL:PRN:ORA		
					L			
			Marijuana	SS	RESPIRATORY (INHALATION)	INHALATION		
			Ibuprofen	C				
			Multiple Vitamins	C				
			Garlic	C				

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	
						(DAILY), PER		
						ORAL		
			Marijuana (Cannabis)	SS				
			Unspecified Birth					
			Control Pills	C				
			Prozac (Fluoxetine					
			Hydrochloride)	C				

Date:02/23/00ISR Number: 3465755-1Report Type:Periodic Company Report #9910543 Age:14 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Dependence Injury	Consumer Health Professional	Zoloft Tablets	PS		ORAL	ORAL	
			Marijuana	SS	RESPIRATORY (INHALATION)	INHALATION		

Date:02/23/00ISR Number: 3469751-XReport Type:Periodic Company Report #9948084 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Health Professional Company Representative	Zoloft Tablets	PS		NOT SPECIFIED	NOT SPECIFIED	
			Marijuana	SS		NOT SPECIFIED		

Date:04/06/00ISR Number: 3484575-5Report 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 Small For Dates Baby	Literature Health Professional	Saquinavir (Saquinavir Mesylate) Stavudine (Stavudine) Lamivudine (Lamivudine) Nelfinavir (Nelfinavir) Delavirdine	PS				

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

(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 Hepatitis C Medication Error Pregnancy Induced Hypertension Small For Dates Baby	Literature Health Professional	Saquinavir (Saquinavir Mesylate) Stavudine (Stavudine) Lamivudine (Lamivudine) Nelfinavir (Nelfinavir) Marijuana (Cannabis) Zidovudine (Zidovudine)	PS				

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,		ORAL			

Paracetamol) SS ORAL SINGLE, ORAL
 Alcohol (Ethanol) SS ORAL SINGLE, ORAL 1 DAY
 Marijuana (Cannabis) SS SINGLE

Date:04/24/00ISR Number: 3494141-3Report Type:Periodic Company Report #9953044 Age:61 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dry Skin Face Oedema Pruritus	Consumer Health Professional	Viagra Tablets	PS		ORAL	50.00 MG	
		Marijuana	SS			L RESPIRATORY (INHALATION) INHALATION		
		Ibuprofen	C					
		Multiple Vitamins	C					
		Garlic	C					

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 International Normalised Ratio Decreased	Health Professional	Coumadin	PS	Dupont Merck Pharmaceutical Co	ORAL	4-16 MG DLY	
		Marijuana(Cannabis)	SS			PO		
		Ni (Baclofen)	C					

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Dulcolax (Bisacodyl) C
 Amitriptyline
 (Amitriptyline) C
 Ni (Oxybutynin) C

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		
		Celebrex (Celecoxib)	SS			ORAL	1400MG SINGLE	
		Marijuana (Cannabis)	SS					
		Cocaine (Cocaine)	SS					
		Aspirin "Bayer" (Acetylsalicylic Acid)	SS			ORAL		
		Tylenol (Paracetamol)	SS			ORAL		

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	Twice 6 MON
	Drug Abuser		Marijuana	SS				
	Drug Interaction		No Concurrent Medications	C				
	Glycosuria							
	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				

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/28/01ISR Number: 3675819-5Report Type:Periodic Company Report #A005968

Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depression Drug Ineffective Nervousness Weight Increased	Consumer Health Professional	Zoloft	PS	Pfizer Pharmaceuticals Inc	ORAL	100.00 MG	
						TOTAL: DAILY:		
			Marijuana	SS		ORAL		

Date:02/28/01ISR Number: 3677067-1Report Type:Periodic Company Report #A027861 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Health	Zoloft	PS	Pfizer			
	Laboratory Test Abnormal	Professional	SS		Pharmaceuticals Inc			
		Marijuana						

Date:02/28/01ISR Number: 3677132-9Report Type:Periodic Company Report #A007530 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Consumer	Zoloft	PS	Pfizer			
	Urine Analysis Abnormal		SS		Pharmaceuticals Inc			
		Marijuana						

Date:03/01/01ISR Number: 3671689-XReport 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 -	Condition Aggravated	Health	Wellbutrin	PS	Glaxo Wellcome	ORAL	100MG	Twice
Initial or Prolonged	Disturbance In Social	Professional				per day	6	MON
Other	Behaviour		Marijuana	SS				
	Drug Interaction		Benadryl	C		ORAL	25MG	As
	Glycosuria					required		
	Movement Disorder							
	Syncope							

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	Foreign	Loxitane Im	PS	Watson Laboratories			
	Blood Alcohol Increased	Health		Inc		INTRAMUSCULAR	50 MG	1 X PER
	Condition Aggravated	Professional				1 DAY, IM	1	DAY
	Drug Ineffective	Company	Alcohol (Ethanol)	SS		ORAL	ORAL	1 DAY
	Head Injury	Representative	Bromazepam	SS				
	Pulmonary Embolism		Lysanxia (Prazepam)	SS			40 MG	1 X PER
						1 DAY		
		Marijuana (Cannabis)	SS			RECTAL	INHALATION	
		Netux						
		(Codeine/Phenyltoloxamine)	SS					
		Rivotril						
		(Clonazepam)	SS			ONE VIAL	1	DAY
		Solian (Amisulpride)	SS			400 MG	1 X	
						PER 1 DAY,		
		Teralithe (Lithium)						

Freedom Of Information (FOI) Report

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	INTRAMUSCULAR	50 MG 1 X PER	
	Aggression	Health	Inc			1 DAY, IM	1 DAY	
	Agitation	Professional				ORAL	ORAL	1 DAY
	Alcoholism	Company	Alcohol (Ethanol)	SS				
	Drug Abuser	Representative	Bromazepam					
	Drug Ineffective		(Bromazepam)	SS				
	Head Injury		Lysanxia (Prazepam)	SS			40 MG 1 X PER	
	Toxicologic Test Abnormal						1 DAY	
		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

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Benzodiazepine,
 Unspec) SS

Date:06/18/01ISR Number: 3741833-4Report Type:Expedited (15-DaCompany Report #2012752 Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Complications Of Maternal Exposure To Therapeutic Drugs	Other	Oxycontin Lortab (Hydrocodone/Acetami nophen)	PS	Purdue Pharma Lp			
	Deafness		Xanax (Alprazolam)	SS				
	Drug Withdrawal Syndrome Neonatal		Marijuana Ecstasy (Methylene Dioxymethamphetamine)	SS				

Date:07/04/01ISR Number: 3752045-2Report Type:Expedited (15-DaCompany Report #2012499 Age:13 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Alcohol Increased Overdose	Health Professional	Morphine Sulfate (Similar To Andas 74-769 And 74-862)	PS				
	Toxicologic Test Abnormal	Other	Ethanol Benzodiazepine Marijuana Metabolites	SS SS				

Date:07/04/01ISR Number: 3752049-XReport Type:Expedited (15-DaCompany Report #2012498 Age:13 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose Blood Alcohol Increased	Health Professional	Morphine Sulfate (Similar To Nda 19-516)	PS				
		Other	Ethanol Benzodiazepine Marijuana Metabolites	SS SS				

Date:07/27/01ISR Number: 3767169-3Report Type:Expedited (15-DaCompany Report #2013545

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Atelectasis Brain Oedema	Health Professional Other	Oxycontin Hydrocodone Bitartrate Ethyl Alcohol Cocaine Diazepam Lidocaine Marijuana	PS	Purdue Pharma Lp			

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

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 Other	Amnesia Cerebrovascular Accident Confusional State Gait Disturbance Medication Error Sluggishness Speech Disorder Vomiting	Other	Xanax (Alprazolam)Tablet Marijuana (Cannabis	PS SS		NASAL NASAL	NASAL NASAL	1 DAY

Date:11/28/01ISR Number: 3831402-XReport Type:Expedited (15-DaCompany Report #2001AP05206

Age:15 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Abuser	Literature Health Professional	Amitriptyline Cocaine Marijuana	PS SS SS				

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 Toxicologic Test	Foreign Abnormal Health Professional Other	Seresta (Oxazepam, Tablet) Alcohol (Ethanol) Cocaine (Cocaine)	PS SS SS		ORAL	ORAL 1 DAY 1 DAY	1 DAY

Lexomil (Bromazepam) SS	1 DAY
Marijuana (Cannabis) SS	1 DAY
Tranxene	
(Clorazepate	
Dipottasium) SS	1 DAY
Valium (Diazepam) SS	1 DAY

Date:01/25/02ISR Number: 3863127-9Report Type:Expedited (15-DaCompany Report #2014078 Age:16 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anoxic Encephalopathy	Health	Oxycontin Cr					
Hospitalization - Initial or Prolonged	Brain Oedema Cardiomegaly	Professional Other	Tablets, 10 Mg (Oxycodone Hydrochloride)					
	Coma		PS			MG UNKNOWN		
	Drug Toxicity		Ecstasy					
	Dyspnoea		(Methylenedioxyamfetamine)					
	Excoriation		SS			MG KNOWN		
	Hepatic Congestion		Alcohol			CC		
	Hepatosplenomegaly		Marijuana					
	Mental Impairment		Caffeine					
	Overdose		Lidocaine					
	Pulmonary Congestion							
	Pulmonary Oedema							
	Spleen Congestion							
	Syncope							
	Toxicologic Test Abnormal							

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/13/02ISR Number: 3876226-2Report Type:Periodic Company Report #2012813 Age: Gender:Female 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)			MG		
			Lortab					
			(Hydrocodone/Acetaminophen)					
			SS					
			Xanax (Alprazolam)					
			SS					
			Marijuana					
			SS					
			Ecstasy (Methylene Dioxymethamphetamine)					
			SS					

Date:02/13/02ISR Number: 3876248-1Report Type:Periodic Company Report #2012756 Age:21 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, 10 Mg (Oxycodone Hydrochloride)	PS		ORAL	MG	PO
			Xanax (Alprazolam)	SS				
			Marijuana	SS				
			Alcohol	SS				
			Lidocaine	SS				
			Nicotine	SS				

Date:02/13/02ISR Number: 3876287-0Report Type:Periodic Company Report #2012847 Age:15 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose	Consumer Other	Oxycontin Cr Tablets, 10 Mg (Oxycodone Hydrochloride)	PS				
			Marijuana	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	Health Professional Other	Morphine Sulfate (Similar To Andas 74-769 And 74-862) (Morphine Sulfate) Er Tablet	PS				
	Drug Interaction		Morphine Sulfate (Similar To Nda 19-516) (Morphine Sulfate) Cr Tablet	SS				
	Hepatic Steatosis		Ethanol (Ethanol)	SS				
	Overdose		Diazepam (Diazepam)	SS				
	Pulmonary Congestion		Marijuana (Cannabis)	SS				
			Desipramine (Desipramine)	SS				

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

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	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Atelectasis	Health	Similar To Andas					
	Completed Suicide	Professional	74-769 And 74-862)					
	Drug Level Above Therapeutic	Other	(Morphine Sulfate)					
	Intentional Overdose		Er Tablet PS					
	Lymphadenopathy		Oxycodone Hydrochloride					
	Pulmonary Granuloma		(Similar To Nda					
	Pulmonary Oedema		20-553) (Oxycodone					
	Toxicologic Test Abnormal		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:03/20/02ISR Number: 3888563-6Report Type:Expedited (15-DaCompany Report #2002-03-0533 Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anger	Study	Peg-Intron					
	Drug Abuser	Health	(Peginterferon					
	Homicide	Professional	Alfa-2b) Injectable					
	Insomnia		Powder PS					
			Ribavirin Capsules SS			SUBCUTANEOUS	132 MCG QWK	
						SUBCUTANEOUS		
						ORAL	400 MG BID	
						ORAL		
			Cocaine SS					
			Marijuana SS					
			Alcohol SS					
			Tylenol C					
			Xanax C					
			Paxil C					
			Ambien (Zolpidem					
			Tartrate) C					

Date:04/12/02ISR Number: 3898882-5Report Type:Expedited (15-DaCompany Report #B0259974A Age:19 YR Gender:Male I/FU:F

Outcome	PT
Hospitalization -	Brain Oedema
Initial or Prolonged	Cerebral Infarction
Disability	Dysarthria
	Dysphagia
	Vasoconstriction

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Vertigo

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Health Professional	Imigran Marijuana	PS SS	Glaxo Wellcome	SUBCUTANEOUS		

Date:05/30/02ISR Number: 3927579-8Report Type:Expedited (15-DaCompany Report #A211570 Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Drug Abuser	Foreign	Viagra Tablets	PS		ORAL	ORAL	
Intervention to	Homicide	Consumer	Ecstasy	SS				
Prevent Permanent Impairment/Damage	Injury Paraphilia		Marijuana	SS				

Date:07/11/02ISR Number: 3948429-XReport Type:Expedited (15-DaCompany Report #A214275 Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required	Delusion	Foreign	Zoloft Tablets	PS		ORAL	50.00 MG	
Intervention to	Hallucination	Health Professional				TOTAL:DAILY:ORAL		
Prevent Permanent Impairment/Damage	Paranoia		Marijuana	SS				

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 Professional	Oxycontin Tablets					
	Cardiac Failure	Other	(Oxycodone Hydrochloride) Cr Tablet	PS		ORAL		
	Congestive Cardiomegaly		Hydrocodone Bitartrate (Similar To Ind 59, 175)					
	Drug Screen Positive		(Hydrocodone Bitartrate) Unknown	SS		ORAL		
	Pleural Effusion		Methadone(Methadone) Unknown	SS		ORAL		
	Pulmonary Oedema		Amitriptyline(Amitriptyline)Tablet	SS		ORAL		
			Valium (Diazepam) Tablet	SS		ORAL		
			Orphenadrine(Orphenadrine) Tablet	SS		ORAL		
			Marijuana(Cannabis) Unknown	SS				

Outcome PT
 Death Cardiomegaly
 Drug Screen Positive
 Drug Toxicity
 Myocardial Fibrosis
 Pulmonary Congestion

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Pulmonary Oedema
 Ventricular Hypertrophy

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Health Professional	Oxycodone Hydrochloride (Similar To Nda 20-553) (Oxycodone Hydrochloride) Propoxyphene (Dextropropoxyphene) Tablet	PS				
Other	Marijuana (Cannabis)	SS				

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Consumer	Peg-Intron (Peginterferon Alfa-2b) Injectable Powder	PS		SUBCUTANEOUS	96 MCG QWK	
	Rebetol (Ribavirin) Injectable Powder	SS		SUBCUTANEOUS	800 MG QD	
	Marijuana	SS		RESPIRATORY (INHALATION) INHALATION		

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Adderall	PS				
	Marijuana	SS				

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 Overdose Toxicologic Test Abnormal	Other	(Oxycodone Hydrochloride) Cr Tablet	PS				
			Hydrocodone Bitartrate (Similar To Ind 59, 175) (Hydrocodone Bitartrate)	SS				
			Methadone (Methadone)	SS				
			Marijuana (Cannabis)	SS				

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/17/02ISR Number: 3995808-0Report Type:Expedited (15-DaCompany Report #NSADSS2002032634

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Apnoea	Literature	Fentanyl (Patch)					
	Body Temperature Increased Bradycardia	Health Professional	(Fentayl)	PS		INGESTION INTENTIONAL ABUSE		
	Coma		Alprazolam					
	Depressed Level Of Consciousness		(Alprazolam)	SS		INTENTIONAL ABUSE		
	Drug Screen Positive		Cocaine	SS		INTENRIONAL ABUSE		
	Electromechanical Dissociation		Marijuana (Cannabis)	SS				
	Intentional Overdose Medication Error Pulse Absent Respiratory Failure							

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 Drug Dependence Drug Withdrawal Syndrome	Other	Mg (Oxycodone Hydrochloride) Cr Tablet	PS		MG		

Faecal Incontinence
 Overdose
 Pain
 Toxicologic Test Abnormal
 Urinary Incontinence

Hydrocodone
 Bitartrate (Similar
 To Ind 59, 175)
 (Hydrocodone
 Bitartrate) SS MG
 Methadone
 (Methadone) SS
 Marijuana (Cannabis) SS
 Alprazolam C

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 Intentional Overdose	Literature Health Professional	Ketalar (Ketamine) Injection Methylenedioxyamphet amine (Methylenedioxyampe tamine) Marijuana (Cannabis)	PS		ORAL	ORAL	
			SS		ORAL	ORAL		
			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
 Death
 Other

PT
 Aggression
 Agitation
 Cardiac Failure
 Delirium
 Loss Of Consciousness
 Overdose

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Polysubstance Abuse

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Consumer	Oxycontin (Oxycodon Hydrochloride) Cr	PS		INTRAVENOUS		
Other	Cocaine (Cocaine) Amitriptyline (Amitriptyline)	SS		INTRAVENOUS		
	Unknown Marijuana (Cannabis)	SS	UNKNOWN		1	DAY
	Unknown	SS	UNKNOWN		1	DAY

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

Age: Gender:Male I/FU:I

Hospitalization -	Accidental Overdose	Health	Oxycontin Tablets				
Initial or Prolonged	Cerebral Infarction	Professional	(Oxycodone				
Disability	Convulsion	Company	Hydrochloride) Cr				
Other	Drug Abuser	Representative	Tablet	PS	INTRAVENOUS	INTRAVENOUS	
Required	Respiratory Depression		Marijuana (Cannabis)	SS	RESPIRATORY		
Intervention to	Skin Ulcer				(INHALATION)	INHALATION	
Prevent Permanent			Amphetamine				
Impairment/Damage			(Amfetamine)	SS			

Date:03/05/03ISR Number: 4071226-4Report Type:Expedited (15-DaCompany Report #USA-2002-0000577 Age:23 YR Gender:Female I/FU:I

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

Date:03/12/03ISR Number: 4075764-XReport Type:Expedited (15-DaCompany Report #2014523 Age:30 YR Gender:Female I/FU:F

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

Wound

Sertraline

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

(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:04/08/03ISR Number: 4091544-3Report Type:Expedited (15-DaCompany Report #USA-2003-0005153 Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Screen Positive	Consumer	Oxycodone					
	Internal Injury	Health	Hydrochloride	PS		MG		
	Polysubstance Abuse	Professional	Amfetamine	SS			MG	
	Road Traffic Accident	Other	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:04/18/03ISR Number: 4098554-0Report 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					
Other	Anxiety	Health	Mg (Oxycodone					
	Back Pain	Professional	Hydrochloride)Cr					

Coma	Other	Tablet	PS	10 MG
Depression		Oxycontin Tablets 40		
Drug Abuser		Mg (Oxycodone		
Drug Dependence		Hydrochloride) Cr		
Drug Screen Positive		Tablet	SS	40 MG, BID
Drug Withdrawal Syndrome		Hydrocodone		
Faecal Incontinence		Bitartrate (Similar		
Insomnia		To Ind 59,		
Overdose		175)(Hydrocodone		
Pain		Bitartrate) Unknown	SS	89 DAY
Sexual Dysfunction		Oxyir Capsules 5 Mg		
Urinary Incontinence		(Oxycodone		
		Hyrochloride) Ir		

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Capsule	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		

Date:04/24/03ISR Number: 4102312-8Report Type:Expedited (15-DaCompany Report #NSADSS2003018777

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Brain Oedema	Other	Duragesic (100 Mcg/					
	Drug Abuser		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:05/09/03ISR Number: 4110546-1Report Type:Expedited (15-DaCompany Report #USA-2002-0000577

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Affect Lability	Consumer	Oxycontin Tablets					
Initial or Prolonged	Affective Disorder	Health	20mg (Oxycodone					
Other	Arthralgia	Professional	Hydrochloride) Cr					
	Asthenia	Other	Tablet	PS			20 MG, UNK,	
	Decreased Appetite						UNKNOWN	
	Depersonalisation		Amfetamine					

Depression	(Amfetamine)	SS	
Disturbance In Attention	Cocaine (Cocaine)	SS	
Drug Abuser	Marijuana (Cannabis)	SS	
Drug Dependence	Tylenol W/Codeine		
Drug Screen Positive	No. 3(Codeine		
Drug Withdrawal Syndrome	Phosphate,		
Hepatic Function Abnormal	Paracetamol) Tablet	SS	UNK, TABLET,
Loss Of Consciousness			UNK
Nausea	Tylox(Oxycodone		
Nephrolithiasis	Terephthalate)		
Paranoia	Tablet	SS	UNK, TABLET
Photosensitivity Reaction	Lortab(Paracetamol,		
Psychotic Disorder	Hydrocodone		
Refusal Of Treatment By Patient	Bitartrate) Tablet	SS	TABLET
Rhinorrhoea	Vicodin(Paracetamol,		
Suicidal Ideation	Hydrocodone		
Suicide Attempt	Bitartrate) Tablet	SS	TABLET
Vomiting	Xanax(Alprazolam)		
Weight Decreased	Tablet	SS	
	Prazac (Prazosin		
	Hydrochloride)		
	Tablet	C	
	Trazodone		
	(Trazodone) Tablet	C	
	Keflex (Cefalexin		

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Monohydrate) Tablet C

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				

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
 Pulmonary Congestion
 Pulmonary Oedema
 Respiratory Arrest
 Toxicologic Test Abnormal

Dextropropoxyphene(D
 extropropoxyphene) SS
 Marijuana(Cannabis) SS

Date:05/16/03ISR Number: 4126585-0Report Type:Periodic Company Report #2003-01-2570 Age:18 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion	Health	Peg-Intron					
		Professional Company Representative	(Peginterferon Alfa-2b) Injectable Powder	PS		SUBCUTANEOUS SUBCUTANEOUS	UNKNOWN	
			Rebetol (Ribavirin) Capsules	SS	ORAL	UNKNOWN	ORAL	
			Marijuana	SS				

Date:05/23/03ISR Number: 4117123-7Report Type:Expedited (15-DaCompany Report #DSA_70099_2003 Age:16 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Brain Oedema		Darvon	PS				
	Haemorrhage		Fentanyl	SS		TRANSDERMAL	100 MCG/HR	TD
	Medication Error		Ritalin	SS				
	Nervous System Disorder		Marijuana	SS		VAR		
	Petechiae							
	Pleural Haemorrhage							
	Pulmonary Congestion							
	Pulmonary Oedema							
	Respiratory Arrest							

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

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 Prevent Permanent Impairment/Damage	Drug Interaction	Professional	(Isotretinoin)	40 Mg PS		ORAL	2 PER DAY	
	Suicidal Ideation		Marijuana (Cannabis)	SS		ORAL	ORAL	

Date:06/12/03ISR Number: 4129317-5Report Type:Expedited (15-DaCompany Report #USA-2002-0000577

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Abdominal Pain Affective Disorder Aggression Anorexia Anxiety Arthralgia Cold Sweat Depersonalisation Depression Disturbance In Attention Drug Abuser Drug Dependence Drug Screen Positive Drug Withdrawal Syndrome Fatigue Haematuria Headache Hepatic Function Abnormal Insomnia Intentional Self-Injury Loss Of Consciousness Muscle Spasms Myalgia Nausea Nephrolithiasis Night Sweats Pain Paranoia Photosensitivity Reaction Psychotic Disorder Renal Pain Rhinorrhoea Suicide Attempt Tremor Vomiting Weight Decreased	Consumer Health Professional Other	Oxycontin Tablets 20 Mg(Oxycodone Hydrochloride)Cr Tablet PS Amfetamine(Amfetamine) e) 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)Tablet C Keflex (Cefalexin Monohydrate)Tablet C				20 MG TABLET TABLET TABLET TABLET TABLET	

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 Coma Drug Abuser Pyrexia Respiratory Failure	Literature Health Professional	Fentanyl (Patch) PS Alprazolam SS			INGESTION - INTENTIONAL ABUSE INTENTIONAL ABUSE		

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Cocaine SS INTENTIONAL
 Marijuana (Cannabis) SS ABUSE

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 Injury		Paxil	PS	Glaxosmithkline	ORAL		
			Cocaine	SS				
			Marijuana	SS				
			Heroin	C				

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	Aggression		Stadol Nasal Spray	PS	Bristol-Myers Squibb			
Other	Chest Pain				Company	NASAL	1 YR	
	Dependence		Stadol Nasal Spray	SS	Bristol-Myers Squibb			
	Depression				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: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
Prevent Permanent Self-Medication
Impairment/Damage

(Amphetamine) SS

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/10/03ISR Number: 4183062-9Report 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		Combivir	PS	Glaxosmithkline			
			Nevirapine	SS				
			Ibuprofen	SS	Glaxosmithkline			
			Marijuana	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	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Abdominal Pain Alcoholism Anxiety	Upper Health Professional	Consumer (Oxycodone Hydrochloride) Cr					
	Arthralgia	Other	Tablet	PS		INTRAVENOUS		INTRAVENOUS
	Depression		Demerol (Pethidine Hydrochloride)	SS		INTRAVENOUS		INTRAVENOUS
	Drug Abuser		Dilaudid (Hydromorphone Hydrochloride)	SS				
	Drug Dependence							
	Drug Tolerance							
	Drug Withdrawal Syndrome							
	Emotional Distress		Cocaine (Cocaine)	SS		INTRAVENOUS		INTRAVENOUS
	Gastritis		Alcohol (Ethanol)	SS		ORAL	12, DAILY,	
	Headache					ORAL		
	Insomnia		Marijuana (Cannabis)	SS				
	Nausea		Percodan (Phenacetin,					
	Pain							
	Polysubstance Dependence		Homatropine					
	Refusal Of Treatment By Patient		Terephthalate, Oxycodone	SS				
	Sickle Cell Anaemia With Crisis		Humulin (Insulin Isophane, Human Biosynthetic,					
	Vomiting		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
 Death
 Hospitalization -
 Initial or Prolonged

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

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

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 Literature Ultram (Tramadol
 Drug Abuser Health Hydrochloride)
 Professional Tablets PS ORAL ORAL
 Distributor Heroin (Diamorphine) SS
 Marijuana (Cannabis) SS RESPIRATORY
 (INHALATION) INHALATION

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 - Accidental Overdose Consumer Oxycontin
 Initial or Prolonged Agitation Health Tablets(Oxycodone
 Other Alcoholism Professional Hydrochloride)Cr
 Anxiety Other Tablet PS ORAL 80 MG, SEE

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	
Drug Dependence	Hydrochloride)	C
Drug Withdrawal Syndrome	Doxepin (Doxepin)	C
Feeling Of Despair	Remeron	
Galactorrhoea	(Mirtazapine)	C
Headache	Trazodone(Trazodone)	C
Mydriasis	Ambien (Zolpidem	
Pain	Tartrate)	C
Pain In Extremity	Zanaflex (Tizanidine	
Polysubstance Abuse	Hydrochloride)	C
Respiratory Rate Decreased	Clonidine (Clonidine)	C
Sedation	Atarax(Hydroxyzine	
Treatment Noncompliance	Hydrochloride)	C
	Ativan (Lorazepam)	C
	Vicodin	C
	Inderal (Propranolol	
	Hydrochloride)	C
	Ultram	C

TEXT, ORAL

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

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
Cigebtab
(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: 4208047-5Report Type:Expedited (15-DaCompany Report #USA-2003-0005884 Age:34 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization -	Accidental Overdose
Initial or Prolonged	Affective Disorder
Other	Agitation
	Alcoholism
	Aneurysm
	Anxiety
	Arthralgia

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Asthenia							
	Back Pain							
	Bipolar Disorder	Consumer	Oxycontin Tablets					
	Blood Glucose Decreased	Health	(Oxycodone					
	Blood Glucose Increased	Professional	Hydrochloride) Cr					
	Blood Prolactin Increased	Other	Tablet	PS		ORAL	80 MG, SEE	
	Bronchitis					TEXT, ORAL		
	Chills							
	Cough		Xanax (Alprazolam)	SS				

Depressed Level Of Consciousness	Cocaine (Cocaine)	SS
	Marijuana (Cannabis)	SS
Depression	Neurontin	
Dizziness	(Gabapentin)	C
Drug Abuser	Flexeril	
Drug Dependence	(Cyclobenzaprine	
Drug Withdrawal Syndrome	Hydrochloride)	C
Dysarthria	Doxepin (Doxepin)	C
Dyspnoea	Remeron	
Dysuria	(Mirtazapine)	C
Eye Disorder	Trazodone	
Feeling Of Despair	(Trazodone)	C
Galactorrhoea	Ambien (Zolpidem	
Gastroenteritis	Tartrate)	C
Headache	Zanaflex (Tizanidine	
Hyperhidrosis	Hydrochloride)	C
Hypertension	Clonidine	
Lethargy	(Clonidine)	C
Ligament Injury	Klonopin	
Logorrhoea	(Clonazepam)	C
Lymphadenopathy	Atarax (Hydroxyzine	
Migraine	Hydrochloride)	C
Multiple Drug Overdose	Ativan (Lorazepam)	C
Mydriasis	Vicodin	C
Nausea	Inderal (Propranolol	
Night Sweats	Hydrochloride)	C
Overdose	Ultram	C
Pain In Extremity	Naprosyn (Naproxen)	C
Polysubstance Abuse	Valium (Diazepam)	C
Pulmonary Congestion	Risperdal	
Pyrexia	(Risperidone)	C
Respiratory Rate Decreased	Depakote (Valproate	
	Semisodium)	C
Sedation	Thiamine (Thiamine)	C
Self-Medication	Mellaril	
Sinusitis	(Thioridazine	
Tachycardia	Hydrochloride)	C
Thirst	Imitrex (Sumatriptan	
Tongue Disorder	Succinate)	C
Treatment Noncompliance	Lithium (Lithium)	C
Ulcer	Seroquel	
Vision Blurred	(Quetiapine)	C
Wheezing	Cogentin	
	(Benzatropine	
	Mesilate)	C
	Tylenol W/Codeine	
	No.3	C
	Albuterol	
	(Salbutamol)	C
	Haldol (Haloperidol)	C
	Imitrex "Glaxo"	
	(Sumatriptan)	C

Freedom Of Information (FOI) Report

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

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		Combivir	PS	Glaxosmithkline	ORAL	450MG Twice	
	Visual Disturbance							
			Nevirapine	SS		ORAL	200MG Twice	
			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: 4211263-XReport Type:Expedited (15-DaCompany Report #US-JNJFOC-20030904400 Age:60 YR Gender:Male I/FU:F

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
Drug Screen Positive

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Drug Toxicity
Grimacing

Miosis	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Pco2 Increased	Literature	Ultram (Tramadol					
Po2 Increased	Health	Hydrochloride)					
Respiratory Arrest	Professional	Tablets	PS		ORAL	ORAL	
	Distributor	Temazepam					
		(Temazepam)	SS		ORAL	ORAL	
		Heroin (Diamorphine)	SS		PARENTERAL	PARENTERAL	
		Ethanol (Ethanol)	SS				
		Marijuana (Cannabis)	SS				

Date:10/15/03ISR Number: 4211291-4Report 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
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

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

	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

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

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

Date:10/24/03ISR Number: 4219748-7Report Type:Expedited (15-DaCompany Report #KII-2003-0003750

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

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:10/28/03ISR 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
Syndrome
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

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Feeling Abnormal	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Formication	Consumer	Oxycontin Tablets	PS		ORAL	80 MG, SEE	
Gait Disturbance	Health				TEXT, ORAL;		
Galactorrhoea	Professional				20 MG, SEE		
Gastroenteritis Viral							
Hallucination, Auditory							

Headache	Other	
Heart Rate Increased		
Hyperhidrosis	Xanax(Alprazolam)	SS
Hypertension	Cocaine(Cocaine)	SS
Lethargy	Marijuana(Cannabis)	SS
Ligament Injury	Neurontin	
Logorrhoea	(Gabapentin)	C
Lymphadenopathy	Flexeril	
Memory Impairment	(Cyclobenzaprine	
Migraine	Hydrochloride)	C
Multiple Drug Overdose	Doxepin (Doxepin)	C
Mydriasis	Remeron(Mirtazapine)	C
Nausea	Trazodone(Trazodone)	C
Night Sweats	Ambien(Zolpidem	
Pain	Tartrate)	C
Pain In Extremity	Zanaflex(Tizanidine	
Pulmonary Congestion	Hydrochloride)	C
Refusal Of Treatment By Patient	Clonidine(Clonidine)	C
Respiratory Arrest	Klonopin(Clonazepam)	C
Respiratory Depression	Atarax(Hydroxyzine	
Respiratory Distress	Hydrochloride)	C
Respiratory Rate Decreased	Ativan(Lorazepam)	C
Sedation	Vicodin	C
Sinusitis	Inderal(Propranolol	
Tremor	Hydrochloride)	C
Ulcer	Ultram	C
Vision Blurred	Naprosyn (Naproxen)	C
Vomiting	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

TEXT; 40 MG,
BID, ORAL

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: 4224155-7Report Type:Expedited (15-DaCompany Report #KII-2003-0003995

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Acidosis Coma Depressed Level Of Consciousness	Health Professional	Oxycontin Cr Hydrocodone Bitartrate (Similar To Id 59,175)	PS				
	Drug Screen Positive		(Hydrocodone Bitartrate,	SS				
	Drug Withdrawal Syndrome		Neurontin (Gabapentin)	SS				
	Haemoptysis		Celexa (Citalopram Hydrobromide)	SS				
	Multiple Drug Overdose		Soma (Carisoprodol)	SS				
	Pco2		Tricyclic Antidepressant	SS				
	Po2		Acetaminohpen (Paracetamol)	SS				
	Tachycardia		Marijuana (Cannabis)	SS				
	Vomiting		Benzodiazepine Derivatives ()	SS				
			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					

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

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: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:11/03/03ISR Number: 4227147-7Report Type:Expedited (15-DaCompany Report #2003-DE-05255GD Age:33 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Literature	Diphenhydramine					
	Completed Suicide		(Diphenhydramine)	PS		RT		
			Aspirin/Butalbital/Caffeine	SS		RT		
			Marijuana (Cannabis)	SS				

Date:11/04/03ISR Number: 4227104-0Report Type:Expedited (15-DaCompany Report #USA-2003-0005884 Age:34 YR Gender:Female I/FU:F

Outcome
 Hospitalization -
 Initial or Prolonged

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Other

PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Accidental Overdose	Consumer	Oxycontin Tablets					
Agitation	Health	(Oxycodone					
Alcohol Withdrawal Syndrome	Professional	Hydrochloride)Cr					
	Other	Tablet	PS		ORAL	SEE IMAGE	
Anxiety		Xanax(Alprazolam)	SS				
Arthralgia		Cocaine(Cocaine)	SS				
Asthenia		Marijuana(Cannabis)	SS				
Asthma		Neurontin					
Bipolar Disorder		(Gabapentin)	C				
Blood Glucose Decreased		Flexeril					
Blood Glucose Increased		(Cyclobenzaprine					
Blood Prolactin Increased		Hydrochloride)	C				
Bronchitis		Doxepin (Doxepin)	C				
Chills		Remeron					
Depressed Level Of Consciousness		(Mirtazapine)	C				
Depression		Trazodone					
Dizziness		(Trazodone)	C				
Drug Abuser		Ambien (Zolpidem					
Drug Dependence		Tartrate)	C				
Drug Withdrawal Syndrome		Zanaflex (Tizanidine					
		Hydrochloride)	C				
Dysarthria		Clonidine					
Dyspnoea		(Clonidine)	C				
Dysuria		Klonopin					

Feeling Jittery	(Clonazepam)	C
Feeling Of Despair	Atarax (Hydroxyzine	
Formication	Hydrochloride)	C
Galactorrhoea	Ativan (Lorazepam)	C
Gastroenteritis	Vicodin	C
Hallucination, Auditory	Inderal (Propranolol	
Headache	Hydrochloride)	C
Heart Rate Increased	Ultram	C
Hyperhidrosis	Naprosyn (Naproxen)	C
Hypertension	Valium (Diazepam)	C
Lethargy	Risperdal	
Logorrhoea	(Risperidone)	C
Lymphadenopathy	Depakote (Valproate	
Migraine	Semisodium)	C
Multiple Drug Overdose	Thiamine (Thiamine)	C
Mydriasis	Mellaril	
Nausea	(Thioridazine	
Neck Pain	Hydrochloride)	C
Night Sweats	Imitrex (Sumatriptan	
Pain	Succinate)	C
Pyrexia	Lithium (Lithium)	C
Respiratory Rate	Seroquel	
Decreased	(Quetiapine)	C
Respiratory Tract	Cogentin	
Congestion	(Benzatropine	
Sedation	Mesilate)	C
Self-Medication	Tylenol W/Codeine	
Sinusitis	No. 3	C
Swollen Tongue	Albuterol	
Thirst	(Salbutamol)	C
Vision Blurred	Haldol (Haloperidol)	C
	Imitrex "Glaxo"	
	(Sumatriptan)	C
	"Hoffman"	

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	

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

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

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 (Watson Laboratories)					
			(Diphenhydramine Hydrochloride)	PS	Watson Laboratories			
			Fiorinal 50/325/40 (Watson Laboratories)					
			(Caffeinen 40 Mg, Aspirin 325 Mg, Butalbital 50 Mg)	SS	Watson Laboratories			
			Marijuana (Cannabis)	SS				

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	Diazepam (Watson					

Health Laboratories)
Professional (Diazepam) Tablet PS Watson Laboratories
Gamma
Hydroxybutyrate() SS
Marijuana(Cannabis) SS

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

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Professional

Product	Role	Manufacturer	Route	Dose	Duration
Alprazolam (Watson Laboratories)					
(Alprazolam) Tablet	PS	Watson Laboratories			
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				

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

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Depression	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Diarrhoea	Consumer	Oxycontin Cr	PS		ORAL	SEE IMAGE	
Dizziness	Health	Xanax (Alprazolam)	SS				
Drug Abuser	Professional	Cocaine (Cocaine)	SS				
Drug Dependence	Other	Marijuana (Cannabis)	SS				
Drug Withdrawal Syndrome		Neurontin					
Dysarthria		(Gabapentin)	C				
Dysphagia		Flexeril					
Dyspnoea		(Cyclobenzaprine					
Dysuria		Hydrochloride)	C				
Ear Discomfort		Doxepin (Doxepin)	C				
Ear Pain		Remeron					
Feeling Abnormal		(Mritazapine)	C				
Feeling Jittery		Trazodone					
Feeling Of Despair		(Trazodone)	C				
Formication		Ambien (Zolpidem					
Galactorrhoea		Tartrate)	C				
Gastroenteritis		Zanaflex (Tizanidine					
Hallucination, Auditory		Hydrochloride)	C				
Headache		Clonidine					
Heart Rate Increased		(Clonidine)	C				
Hyperhidrosis		Klonopin					
Hypertension							
Irritability							

Laryngitis	(Clonazepam)	C	
Lethargy	Atarax (Hydroxyzine		
Logorrhoea	Hydrochloride)	C	
Lymphadenopathy	Ativan (Lorazepam)	C	
Migraine	Vicodin	C	
Multiple Drug Overdose	Inderal (Propranolol		
Muscle Spasms	Hydrochloride)	C	
Mydriasis	Ultram	C	
Nausea	Naprosyn (Naproxen)	C	
Neck Pain	Valium (Diazepam)	C	
Night Sweats	Risperdal		
Pain	(Risperidone)	C	
Pain In Extremity	Depakote (Valproate		
Pharyngolaryngeal Pain	Semisodium)	C	
Postnasal Drip	Thiamine (Thiamine)	C	
Productive Cough	Mellaril		
Psychomotor Hyperactivity	(Thioridazine		
Pyrexia	Hydrochloride)	C	
Respiratory Rate	Imitrex (Sumatriptan		
Decreased	Succinate)	C	
Respiratory Tract	Lithium (Lithium)	C	
Congestion	Seroquel		
Sedation	(Quetiapine)	C	
Self-Medication	Cogentin		
Sinusitis	(Benzatropine		
Thirst	Mesilate)	C	
Tongue Disorder	Tylenol W/Codeine		
Tremor	No. 3	C	
Vision Blurred	Albuterol		
	(Salbutamol)	C	
	Haldol (Haloperidol)	C	
	Imitrex		
	(Sumatriptan)	C	Glaxo
	Librium		
	(Chlordiazepoxide		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Hydrochloride)	C	Hoffman
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

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
Death	Alcohol Poisoning Cardiomegaly Drug Abuser

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

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

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	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aortic Injury	Health	Oxycodone					
	Cardio-Respiratory Arrest	Professional	Hydrochloride					
	Contusion	Other	(Similar To Nda					
	Drug Screen Positive		20-553)(Oxycodone					
	Emphysema		Hydrochloride)	PS				
	Excoriation		Cocaine (Cocaine)	SS				
	Fracture		Methadone					
	Haemothorax		(Methadone)	SS				
	Injury		Marijuana (Cannibas)	SS				
	Intracranial Injury							
	Laceration							
	Peritoneal Haemorrhage							
	Road Traffic Accident							
	Splenic Injury							
	Subarachnoid Haemorrhage							

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	Health	Oxycodone					
	Injury	Professional	Hydrochooride(Simila					
	Toxicologic Test Abnormal	Other	r 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 -	Accidental Overdose
Initial or Prolonged	Agitation
Other	Alcohol Withdrawal Syndrome

Anxiety
 Arthralgia
 Asthenia
 Asthma

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Adverse Event	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Bipolar I Disorder							
Blood Glucose Decreased							
Blood Glucose Increased	Consumer	Oxycontin Tablets					
Blood Prolactin Increased	Health	(Oxycodone					
Bronchitis	Professional	Hydrochloride) Cr					
Chills	Other	Tablet	PS		ORAL	80 MG, SEE	
Depressed Level Of Consciousness						TEXT, ORAL	
Depression		Xanax (Alprazolam)	SS				
Dizziness		Cocaine (Cocaine)	SS				
Drug Abuser		Marijuana (Cannabis)	SS				
Drug Dependence		Neurontin					
Drug Withdrawal Syndrome		(Gabapentin)	C				
Dysarthria		Flexeril					
Dysphagia		(Cyclobenzaprine					
Dyspnoea		Hydrochloride)	C				
Dysuria		Doxepin (Doxepin)	C				
Feeling Jittery		Remeron					
Feeling Of Despair		(Mirtazapine)	C				
Formication		Trazodone					
Galactorrhoea		(Trazodone)	C				
Gastroenteritis		Ambien (Zolpidem					
Hallucination, Auditory		Tartrate)	C				
Headache		Zanaflex (Tizanidine					
Heart Rate Increased		Hydrochloride)	C				
Hyperhidrosis		Clonidine					
Hypertension		(Clonidine)	C				
Irritability		Klonopin					
Lethargy		(Clonazepam)	C				
Logorrhoea		Atarax (Hydroxyzine					
Lymphadenopathy		Hydrochloride)	C				
Mania		Ativan (Lorazepam)	C				
Migraine		Vicodin	C				
Multiple Drug Overdose		Inderal (Propranolol					
Muscle Spasms		Hydrochloride)	C				
Mydriasis		Ultram	C				
Nausea		Naprosyn (Naproxen)	C				
Neck Pain		Valium (Diazepam)	C				
Night Sweats		Risperdal					
Pain		(Risperidone)	C				
Paraesthesia Oral		Depakote (Valproate					
Pharyngolaryngeal Pain		Semisodium)	C				
Psychomotor Hyperactivity		Thiamine (Thiamine)	C				
Pulmonary Congestion		Mellaril					
Pupils Unequal		(Thioridazine					

Pyrexia	Hydrochloride)	C
Respiratory Rate	Imitrex (Sumatriptan	
Decreased	Succinate)	C
Sedation	Lithium (Lithium)	C
Sinusitis	Seroquel	
Thirst	(Quetiapine)	C
Vision Blurred	Cogentin	
	(Benzatropine	
	Mesilate)	C
	Tylenol W/Codine No.	
	3	C
	Albuterol	
	(Salbutamol)	C
	Haldol (Haloperidol)	
	Tablet	C
	Imitrex "Glaxo"	

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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

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

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

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 Other	Oxycontin Tablets (Oxycodone Hydrochloride)	PS		ORAL	ORAL	
			Ethanol (Ethanol)	SS				
			Marijuana (Cannabis)	SS				
			Cocaine (Cocaine)	SS				

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 Other	Oxycontin Tablets (Oxycodone Hydrochloride)	PS				
			Marijuana (Cannabis)	SS				

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					
	Multiple Drug Overdose	Professional	Hydrochloride					
		Other	(Similar To Nda 20-553) (Oxycodone Hydrochloride)	PS				
			Alprazolam (Alprazolam)	SS				
			Caffeine (Caffeine)	SS				
			Ephedrine (Ephedrine)	SS				
			Acetaminophen (Paracetamol)	SS				
			Dextromethorphan (Dextromethorphan)	SS				
			Chlorpheniramine (Chlorphenamine)	SS				

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Levorphanol
(Levorphanol) SS
Marijuana (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
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Other Drug Abuser Health Oxycontin Tablets 20
 Mental Impairment Professional Mg(Oxycodone
 Company Hydrochloride) PS 20 MG, Q12H
 Representative Pcp (Phenobarbital,
 Codeine Phosphate,
 Phenaz) SS
 Marijuana (Cannabis) SS 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	Accidental Overdose	Consumer	Oxycontin Tablets					
Other	Drug Abuser	Health	(Oxycodone					
		Professional	Hydrochloride)	PS		40 MG, Q12H		
		Other	Oxycodone					
			Hydrochloride					
			(Similar To Nda					
			20-553) Oxycodone					
			Hydrochloride)	SS		5 MG		
			Xanax (Alprazolam)	SS				
			Marijuana (Cannabis)	SS				
			Alcohol (Ethanol)	SS				
			Lidocaine					
			(Lidocaine)	SS				
			Nicotine (Nicotine)	SS				

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	Accidental Overdose	Consumer	Oxycontin Tablets					
Other	Drug Abuser	Other	(Oxycodone					
			Hydrochloride)	PS	ORAL	ORAL		
			Marijuana (Cannabis)	SS		INHALATION		
			Alcohol (Ethanol)	SS	ORAL	ORAL		

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	Oxycodone					
		Professional	Hydrochloride					
			(Similar To Nda					
			20-553) Oxycodone					
			Hydrochloride)	PS				
			Methadone					
			(Methadone)	SS				

Freedom Of Information (FOI) Report

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: 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)	PS	ORAL	ORAL		
			Darvocet-N (Paracetamol) SS Alcohol (Ethanol) SS Marijuana (Cannabis) SS Barbiturates SS					

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)	PS				
			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 Consumer Oxycontin Tablets
Judgement Impaired Other (Oxycodone

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Hydrochloride) PS
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
(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 - Professional (Oxycodone
Initial or Prolonged Company Hydrochloride) PS
Representative Hydrocodone
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)					

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

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: 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
 Company Hydrochloride) PS 80 MG, SEE
 Representative TEXT,
 Marijuana (Cannabis) SS

Date:12/17/03ISR Number: 4272387-4Report Type:Periodic Company Report #KII-2002-0003848 Age:53 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Abnormal Behaviour	Health	Oxycontin Tablets					
Initial or Prolonged	Heart Rate Decreased	Professional	(Oxycodone	PS				
Other	Intentional Overdose		Hydrochloride)					
	Lethargy		Methadone (Mthadone)	SS				
	Multiple Drug Overdose		Valium (Diazepam)	SS				
	Somnolence		Xanax (Alprazolam)	SS				
			Alcohol (Ethanol)	SS				
			Marijuana	SS				
			Cocaine (Cocaine)	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		

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FDA - Adverse Event Reporting System (AERS)
 Freedom Of Information (FOI) Report

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					
	Pain	Professional	Hydrochloride)	PS	ORAL	20 MG, SEE		

Respiratory Depression
Weight Increased

Other

Marijuana (Cannabis) SS

TEXT, ORAL

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

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

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Bipolar I Disorder
Blood Glucose Decreased

Outcome	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Blood Glucose Increased	Consumer	Oxycontin Tablets					
Blood Prolactin	Health	(Oxycodone					
Bronchitis	Professional	Hydrochloride) Cr					

Depressed Level Of	Other	Tablet	PS
Consciousness		Xanax (Alprazolam)	SS
Depression		Cocaine (Cocaine)	SS
Dizziness		Marijuana (Cannabis)	SS
Drug Abuser		Neurontin	
Drug Dependence		(Gabapentin)	C
Drug Withdrawal Syndrome		Flexeril	
Dysarthria		(Cyclobenzaprine	
Dyspnoea		Hydrochloride)	C
Dysuria		Doxepin (Doxepin)	C
Feeling Abnormal		Remeron	
Feeling Jittery		(Mirtazapine)	C
Formication		Trazodone	
Galactorrhoea		(Trazodone)	C
Gastroenteritis		Ambien (Zolpidem	
Hallucination, Auditory		Tartrate)	C
Heart Rate Increased		Zanaflex (Tizanidine	
Hyperhidrosis		Hydrochloride)	C
Hypertension		Clonidine	
Lethargy		(Clonidine)	C
Logorrhoea		Klonopin	
Lymphadenopathy		(Clonazepam)	C
Migraine		Atarax (Hydroxyzine	
Multiple Drug Overdose		Hydrochloride)	C
Mydriasis		Ativan (Lorazepam)	C
Nausea		Vicodin	C
Night Sweats		Inderal (Propranolol	
Pain		Hydrochloride)	C
Paraesthesia Oral		Ultram	C
Pyrexia		Naprosyn (Naproxen)	C
Respiratory Rate		Valium (Diazepam)	C
Decreased		Risperdal	
Respiratory Tract		(Risperidone)	C
Congestion		Depakote (Valproate	
Sedation		Semisodium)	C
Sinusitis		Thiamine (Thiamine)	C
Thirst		Mellaril	
Treatment Noncompliance		(Thioridazine	
Tremor		Hydrochloride)	C
Vision Blurred		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

SEE IMAGE

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Librium "Hoffman"
 (Chlordiazepoxide
 Hydrochloride) C
 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:12/18/03ISR 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 Other	Health Professional	Oxycodone Hydrochloride (Similar To Nda 20-553)(Oxycodone Hydrochloride) Diazepam (Diazepam) Valproic Acid/Valproic Acid) Mirtazapine (Mirtazapine) Topiramate (Topiramate) Marijuana (Cannabis)	PS SS SS SS SS 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	Multiple Drug Overdose	Literature	Oxycodone	PS				
Life-Threatening		Health Professional	Methadone	SS				
			Doxepin	SS				
			Diazepam	SS				
			Marijuana	SS				

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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 Professional	Alprazolam	SS				
	Pulmonary Oedema		Marijuana	SS				

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 -	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
	Duodenitis
	Dysarthria
	Dyspnoea
	Dysuria
	Feeling Jittery
	Feeling Of Despair

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
 Paraesthesia Oral
 Pulmonary Congestion
 Pyrexia

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Respiratory Rate

Decreased

Sedation

Sinusitis

Thirst

Vision Blurred

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Consumer	Oxycontin Tablets					
Health	(Oxycodone					
Professional	Hydrochloride) Cr					
Other	Tablet PS			SEE IMAGE		
	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				
	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

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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:01/22/04ISR Number: 4278860-7Report 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 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

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Dysuria
 Feeling Jittery
 Feeling Of Despair

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
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Fibromyalgia	Consumer	Oxycontin Tablets	
Formication	Other	(Oxycodone	
Galactorrhoea		Hydrochloride) Cr	
Gastritis		Tablet PS	
Gastroenteritis		Xanax (Alprazolam)	SS
Hallucination, Auditory		Cocaine (Cocaine)	SS
Headache		Marijuana (Cannabis)	SS
Heart Rate Increased		Neurontin	
Hyperhidrosis		(Gabapentin)	C
Hypertension		Flexeril	
Lethargy		(Cyclobenzaprine	
Logorrhoea		Hydrochloride)	C
Lymphadenopathy		Doxepin (Doxepin)	C
Migraine		Remeron	
Multiple Drug Overdose		(Mirtazapine)	C
Mydriasis		Trazodone	
Nausea		(Trazodone)	C
Neck Pain		Ambien (Zolpidem	
Night Sweats		Tartrate)	C
Pain		Zanaflex (Tizanidine	
Paraesthesia Oral		Hydrochloride)	C
Pulmonary Congestion		Clonidine	
Pyrexia		(Clonidine)	C
Respiratory Rate		Klonopin	
Decreased		(Clonazepam)	C
Sedation		Atarax (Hydroxyzine	
Self-Medication		Hydrochloride)	C
Sinusitis		Ativan (Lorazepam)	C
Thirst		Vicodin	C
Treatment Noncompliance		Inderal (Propranolol	
Vision Blurred		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

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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:02/06/04ISR Number: 4289361-4Report Type:Expedited (15-DaCompany Report #KII-2003-0007093

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Blood Potassium Decreased Blood Pressure Diastolic Decreased	Study Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-553) (Oxycodone Hydrochloride)					
	Drug Screen Positive Heart Rate Increased Intentional Overdose Lethargy Miosis Multiple Drug Overdose Oxygen Saturation Decreased Pruritus Somnolence		Benzodiazepine Derivatives Marijuana (Cannabis) Cocaine (Cocaine)	PS SS SS SS				

Other	Disturbance In Attention	Hydrochloride) Cr			
	Drug Dependence	Tablet	PS	ORAL	20 MG, BID,
	Drug Ineffective			ORAL	
	Drug Withdrawal Syndrome	Alcohol(Ethanol)	SS		
	Hallucination, Auditory	Marijuana(Cannabis)	SS		
	Insomnia	Cocaine (Cocaine)	SS		
	Memory Impairment	Norco	C		
	Pain	Xanax (Alprazolam)	C		
	Paranoia				
	Polysubstance Abuse				
	Psychotic Disorder				
	Schizophrenia, Paranoid				
	Type				
	Weight Decreased				

Date:02/26/04ISR Number: 4308615-6Report Type:Periodic Company Report #030612-PM0076-00 Age:35 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Intentional Drug Misuse	Literature	Desoxyn					
		Health	(Methamphetamine					
		Professional	Hydrochloride)	PS		ORAL		P.O.
		Other	Marijuana	SS		ORAL		P.O.

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/26/04ISR Number: 4308639-9Report Type:Periodic Company Report #030612-PM0078-00 Age:40 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Abuser	Literature	Desoxyn					
		Health	(Methamphetamine					
		Professional	Hydrochloride)	PS		ORAL		P.O.
		Other	Methylenodiouxmetha					
			mphetamine	SS				P.O.
			Marijuana	SS				INHALATION

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
 Dysarthria
 Dyspnoea
 Dysuria
 Feeling Jittery
 Feeling Of Despair
 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

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Pain	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Paraesthesia Oral	Consumer	Oxycontin Tablets					
Pulmonary Congestion	Health	(Oxycodone					
Pyrexia	Professional	Hydrochloride) Cr					
Respiratory Rate	Other	Tablet	PS		ORAL	80 MG, SEE	
Decreased						TEXT, ORAL;	
Sedation						20 MG, SEE	
Self-Medication						TEXT,	
Sinusitis						UNKNOWN; 40	
Thirst							
Vision Blurred							
	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
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
 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: 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:04/01/04ISR Number: 4333482-4Report Type:Expedited (15-DaCompany Report #KII-2003-0008869

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Agitation	Study	Morphine Sulfate					
Initial or Prolonged	Blood Creatinine	Health	(Similar To Nda					
Other	Increased	Professional	19-516)(Morphine					
	Coma	Other	Sulfate) Unknwon PS					
	Cyanosis		Benzodiazepine					
	Drug Screen Positive		Derivaties SS					

Hypotension
Overdose
Pulmonary Oedema
Vomiting

Marijuana (Cannabis) SS
Amphetamine
(Amphetamine) C
Antidepressants C

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Sri 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
 Logorrhoea
 Lymphadenopathy
 Medication Error
 Migraine
 Mydriasis
 Night Sweats
 Pain
 Pyrexia
 Respiratory Rate
 Decreased
 Respiratory Tract
 Congestion
 Sedation

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Sinusitis

Thirst

Tongue Disorder

Tremor

Vision Blurred

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Consumer	Oxycontin Tablets					
Health Professional	(Oxycodone Hydrochloride) Cr					
Other	Tablet PS		ORAL	SEE IMAGE		
	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	
	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"

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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
Bromdie, Salbutamol

Sulfate) C
 Tegretol
 (Carbamazepine) C
 Protonix
 (Pantoprazole) C

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

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Consumer	Oxycontin Tablets					
Health	(Oxycodone					
Professional	Hydrochloride) Cr					
Other	Tablet	PS		ORAL	80 MG, SEE	
				TEXT, ORAL		
	Xanax (Alprazolam)	SS				

Lipase Increased	Cocaine(Cocaine)	SS
Logorrhoea	Marijuana(Cannabis)	SS
Lymphadenopathy	Neurontin	
Mental Disorder	(Gabapentin)	C
Mental Status Changes	Flexeril	
Migraine	(Cyclobenzaprine	
Multiple Drug Overdose	Hydrochloride)	C
Mydriasis	Doxepin (Doxepin)	C
Night Sweats	Remeron	
Pain	(Mirtazapine)	C
Paraesthesia Oral	Trazodone	
Respiratory Rate	(Trazodone)	C
Decreased	Ambien (Zolpidem	
Respiratory Tract	Tartrate)	C
Congestion	Zanaflex (Tizanidine	
Sedation	Hydrochloride)	C
Sinusitis	Clonidine	
Thirst	(Clonidine)	C
Tremor	Vicodin	C
Ultrasound Scan Abnormal	Inderal (Propranolol	
Vision Blurred	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

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

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Wheezing

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Consumer Health Professional Other	Oxycontin Tablets 20mg (Oxycodone Hydrochloride) Cr 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:04/28/04ISR 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	Literature	Ultram (Tramadol Hydrochloride) Tablets PS			ORAL	ORAL	
	Drug Abuser Overdose	Health Professional Distributor	Heroin (Diamorphine) SS					
			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 Delusion Homicide Mental Disorder Suicidal Ideation	Consumer	Effexor (Venlafaxine Hydrochloride, Tablet) Marijuana (Cannabis,)	PS SS		ORAL ORAL RESPIRATORY (INHALATION) INHALATION		

Date:05/12/04ISR Number: 4359389-4Report Type:Expedited (15-DaCompany Report #HQWYE661130APR04

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

Outcome	PT
Death	Cardio-Respiratory Arrest Drug Abuser

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Drug Interaction
Drug Toxicity

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Health Professional Company Representative	Effexor (Venlafaxine Hydrochloride, Tablet) Codeine (Codeine,) Heroin (Diamorphine,) Marijuana (Cannabis,) Morphine (Morphine,)	PS SS SS		ORAL	SEE IMAGE	

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 Other	Abnormal Behaviour Accidental Overdose Agitation Alcohol Withdrawal Syndrome Anxiety Arthralgia Asthma Bipolar I Disorder Blood Glucose Decreased Blood Glucose Increased Blood Prolactin Increased

Bronchitis
 Chills
 Depressed Level Of
 Consciousness
 Depression
 Drug Abuser
 Drug Dependence
 Drug Ineffective
 Drug Withdrawal Syndrome
 Duodenitis
 Dysarthria
 Dyspepsia
 Dysuria
 Galactorrhoea
 Gastritis
 Hallucination, Auditory
 Headache
 Hypertension
 Inadequate Analgesia
 Insomnia
 Lymphadenopathy
 Mental Disorder
 Migraine
 Mydriasis
 Neck Pain
 Night Sweats
 Overdose
 Pain
 Paraesthesia Oral
 Psychomotor Hyperactivity
 Pulmonary Congestion

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Respiratory Rate Decreased Sedation Sinusitis Thirst Vision Blurred	Report Source Consumer Health Professional Other	Product Oxycontin Tablets (Oxycodone Hydrochloride) Cr Tablet PS Xanax (Alprazolam) SS Cocaine (Cocaine) SS Marijuana (Cannabis) SS Neurontin (Gabapentin) C Flexeril (Cyclobenzaprine Hydrochloride) C Doxepin (Doxepin) C Remeron (Mirtazapine) C	Role	Manufacturer	Route	Dose	Duration	
					ORAL		SEE IMAGE	

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
 (Benztropine
 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)

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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 (Icotic
 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:05/27/04ISR 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 Hydrochloride) Cr					
	Alcohol Withdrawal Syndrome	Professional Other	Tablet PS			ORAL	ORAL	
	Confusional State Drug Screen Positive False Positive Laboratory Result		Cyclobenzaprine (Cyclobenzaprine) Phenothiazine (Phenothiazine)	SS		ORAL	ORAL	
	Hallucination Heart Rate Increased Mydriasis Pyrexia Restlessness		Marijuana (Cannabis)	SS				

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
Hospitalization - Initial or Prolonged	Back Pain Delusion
Other	Disturbance In Attention Drug Abuser Drug Dependence Drug Ineffective Drug Withdrawal Syndrome Feeling Abnormal Hallucination, Auditory Insomnia Major Depression

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Memory Impairment

Pain

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Psychotic Disorder		Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Schizophrenia, Paranoid		Consumer	Oxycontin Tablets					
Type	Health	(Oxycodone						
Weight Fluctuation	Professional	Hydrochloride)Cr						
	Other	Tablet	PS		ORAL	20 MG, BID,		
					ORAL			
		Alcohol (Ethanol)	SS					
		Marijuana (Cannabis)	SS					
		Cocaine (Cocaine)	C					
		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	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Anxiety	Study	Oxycodone					
Initial or Prolonged	Blood Glucose Increased	Health	Hydrochloride					
Other	Body Temperature	Professional	(Similar To Nda					
	Increased	Other	20-553) (Oxycodone					
	Diarrhoea		Hydrochloride)	PS		ORAL	ORAL	
	Drug Abuser		Marijuana (Cannabis)	SS		RESPIRATORY		
	Gait Disturbance					(INHALATION)	INHALATION	
	Hyperventilation		Mushroom()	SS		ORAL	ORAL	
	Metabolic Acidosis		Tramadol (Tramadol)	C				
	Nausea		Oral Contraceptive					
	Polysubstance Abuse		Nos (Oral					
	Refusal Of Treatment By		Contraceptive Nos)	C				
	Patient							
	Respiratory Alkalosis							
	Tremor							
	Urine Ketone Body Present							
	Vomiting							
	White Blood Cell Count							
	Increased							

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 -	Acute Respiratory Failure	Study	Morphine Sulfate					
Initial or Prolonged	Blood Ph Decreased	Other	(Similar To Nda					
Other	Lethargy		19-516 (Morphine					
	Pco2 Increased		Sulfate)	PS				
	Pneumonia		Methadone					
	Polysubstance Abuse		(Methadone)	SS				
	Somnolence		Marijuana (Cannabis)	SS				

Vomiting

Amfetamine
(Amfetamine) SS
Benzodiazepine
Derivatives SS

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

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	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Abnormal Behaviour Aggression Agitation	Study Health Professional Other	Oxycontin Tablets(Oxycodone Hydrochloride) Cr Tablet PS Benzodiazepine Derivatives () Baclofen (Baclofen) Docusate Sodium (Docusate Sodium) Marijuana (Cannabis) Tricyclic Antidepressants() Ultram (Tramadol Hydrochloride) Antiepileptics ()					
	Anger				ORAL	ORAL		
	Aspartate							
	Aminotransferase Increased			SS	ORAL	ORAL		
	Back Pain			SS	ORAL	ORAL		
	Blood Alkaline					ORAL		
	Phosphatase Increased			SS				
	Blood Glucose Increased			SS				
	Blood Pressure Systolic Increased			SS				
	Blood Urea Increased			SS				
	Body Temperature Decreased			SS				
	Convulsion							
	Delirium							
	Disorientation							
	Drug Abuser							
	Drug Withdrawal Syndrome							
	Grunting							
	Hyperhidrosis							
	Loss Of Consciousness							
	Moaning							
	Overdose							
	Patient Restraint							
	Pupillary Reflex Impaired							
	Somnolence							
	Stupor							
	Tremor							
	Urinary Incontinence							
	White Blood Cell Count Increased							
	White Blood Cells Urine Positive							

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					
Other	Multiple Drug Overdose	Health Professional	(Oxycodone 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					

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

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 Professional	(Oxycodone Hydrochloride)	PS				
	Loss Of Consciousness	Other	Morphine Sulfate					
	Multiple Drug Overdose	(Similar To Nda						
	Accidental	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: 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	Consumer	Oxycontin Tablets					
	Multiple Drug Overdose	Health Professional	(Oxycodone Hydrochloride) PS					
		Other	Alcohol (Ethanol) SS					
			Marijuana (Cannabis) 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 (Methylenedioxyamphetamine) SS					
			Cocaine (Cocaine) SS					
			Flexeril (Cyclobenzaprine Hydrochloride) SS					

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

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	Consumer	Oxycontin Tablets					
	Other		(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	Consumer	Oxycontin Tablets					
		Other	(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	Accidental Overdose	Consumer	Oxycontin Tablets					
Other	Drug Abuser	Health	(Oxycodone Hydrochloride)	PS		UNKNOWN	UNK UNK, UNK;	
	Drug Dependence	Professional				UNKNOWN		
	Multiple Drug Overdose	Other						
			Roxicet (Paracetamol, Oxycodone Hydrochloride)	SS	UNKNOWN	5 MG DAILY;		
			Alprazolam (Alprazolam)	SS	UNKNOWN	UNK UNK, UNK;		
			Acetaminophen (Paracetamol)	SS	UNKNOWN	UNK UNK, UNK;		
			Marijuana (Cannabis)	SS	UNKNOWN	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	(Oxycodone Hydrochloride)	PS		UNKNOWN	UNK MG, UNK;	
		Professional				UNKNOWN		
		Other						

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Metamfetamine (Metamfetamine)	SS	UNKNOWN	UNK UNK, UNK;
		UNKNOWN	

Acetaminophen (Paracetamol)	SS	UNKNOWN	UNK UNK, UNK;
		UNKNOWN	
Marijuana (Cannabis)	SS	UNKNOWN	UNK UNK, UNK;
		UNKNOWN	
Ethanol (Ethanol)	SS	UNKNOWN	UNK UNK, UNK;
		UNKNOWN	
Benzodiazepine Derivatives	SS	UNKNOWN	UNK UNK, UNK;
		UNKNOWN	

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				
		Other	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	Oxycodone Hydrochloride					
		Other	(Similar To Nda 20-553) (Oxycodone Hydrochloride)	PS				
			Marijuana (Cannabis)	SS				

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				

Other	Drug Abuser	Consumer	Oxycontin Tablets	
		Other	(Oxycodone Hydrochloride) PS	MG
			Marijuana (Cannabis) SS	
			Cocaine (Cocaine) SS	
			Methylenedioxyamphet amine	
			(Methylenedioxyamphe tamine) SS	

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

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					
			Methylenedioxyamphet amine					
			(Methylenedioxyamphe tamine) 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
Methylenedioxyamphet
amine
(Methylenedioxyamphe
tamine) SS

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 Methylenedioxyamphet amine (Methylenedioxyamphe tamine) SS					

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

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
(Methylenedioxyampheta-
mine) 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 Polysubstance Abuse	Consumer Other	Oxycontin Tablets (Oxycodone Hydrochloride) PS Marijuana (Cannabis) SS					

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 Other	Oxycontin Tablets (Oxycodone Hydrochloride) PS Marijuana (Cannabis) SS Opioids SS			MG,		

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 Multiple Drug Overdose Other	Health Professional Other	Oxycodone Hydrochloride (Similar To Nda 20-553) (Oxycodone Hydrochloride) PS Hydrocodone Bitartrate (Similar					

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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					

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: 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	Oxycontin Tablets					
		Other	(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	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride) PS Marijuana (Cannabis) SS Cocaine (Cocaine) SS Methylenedioxyamphet amine (Methylenedioxypheta mine) SS		MG			

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 Marijuana (Cannabis) SS Cocaine (Cocaine) SS Methylenedioxyamphet amine (Methylenedioxyamphe tamine) SS		MG			

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 Marijuana (Cannabis) SS Cocaine (Cocaine) SS Methylenedioxyamphet amine		MG			

(Methylenedioxyamph
tamine) SS

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

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 Marijuana (Cannabis) SS Cocaine (Cocaine) SS Methylenedioxyamphet amine (Methylenedioxyamph tamine) SS			MG		

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 Marijuana (Cannabis) SS Cocaine (Cocaine) SS Methylenedioxyamphet amine (Methylenedioxyamph tamine) SS			MG		

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 (Methylenedioxyamph 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 (Methylenedioxyamphe tamine)	SS				

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

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 (Methylenedioxyamphe 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				

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
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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					

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

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

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 (Methylenedioxyamphe tamine) SS					

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

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
(Methylenedioxyamphe
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 (Methylenedioxyamphe tamine)	SS				

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: 4397473-XReport Type:Periodic Company Report #USA-2004-0012939 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				

Freedom Of Information (FOI) Report

Date:06/21/04ISR Number: 4397477-7Report Type:Periodic Company Report #USA-2004-0012940 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				
			Methylenedioxyamphetamine (Metylenedioxyamphetamine)	SS				

Date:06/21/04ISR Number: 4397480-7Report Type:Periodic Company Report #USA-2004-0012941 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				
			Methylenedioxyamphetamine (Methylenedioxyamphetamine)	SS				

Date:06/21/04ISR Number: 4397482-0Report Type:Periodic Company Report #USA-2004-0012942 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				
			Methylenedioxyamphetamine (Methylenedioxyamphetamine)	SS				

Date:06/21/04ISR Number: 4397485-6Report Type:Periodic Company Report #USA-2004-0012943 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

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Freedom Of Information (FOI) Report

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				

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Freedom Of Information (FOI) Report

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				

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				

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

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
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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 Methylenedioxyeamphe tamine (Methylenedioxyamphe tamine) SS					

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 Methylenedioxyamphet amine (Methylenedioxyamphe tamine) SS					

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Freedom Of Information (FOI) Report

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
Methylenedioxyamphet
amine
(Methylenedioxyamphe
tamine) 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					

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					

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Freedom Of Information (FOI) Report

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	Health	Oxycodone					
Other	Accidental	Professional	Hydrochloride					
		Other	(Similar To Nda					
			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	(Oxycodone					
		Professional	Hydrochloride)	PS				
		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: 4398031-3Report Type:Periodic Company Report #USA-2003-0009144 Age:23 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Intentional Overdose	Consumer	Oxycontin Tablets					
	Health Professional Other	(Oxycodone Hydrochloride) Hydrocodone Bitartrate (Similar To Ind 59,175) (Hydrocodone Bitartrate)	PS		ORAL	80 MG, ORAL		
								SS

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Fluoxetine (Fluoxetine) SS
 Promethazine (Promethazine) SS
 Marijuana (Cannabis) SS
 Ethanol (Ethanol) SS
 Amitriptyline (Amitriptyline) SS
 Caffeine (Caffeine) SS
 Nortriptyline (Nortriptyline) SS
 Nicotine (Nicotine) SS

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) Hydrocodone Bitartrate (Similar To Ind 59,175) (Hydrocodone Bitartrate)	PS					
								SS
								SS
								SS
								SS
								SS
								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
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Death Accidental Overdose Health Oxycodone
Professional Hydrochloride
Other Oxycodone PS MG
Hydrochloride)
Hydrocodone
Bitartrate

(Hydrocodone
Bitartrate) SS
Carisoprodol
(Carisoprodol) SS
Meprobamate
(Meprobamate) SS
Ethanol (Ethanol) SS
Nicotine (Nicotine) SS
Propoxyphene
(Dextropropoxyphene
) SS
Amitriptyline
(Amitriptyline) SS
Marijuana (Cannabis) SS

RESPIRATORY
(INHALATION) INHALATION

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Valium (Dizaepam) SS
Zoloft (Sertraline
Hydrochloride) SS
Caffeine (Caffeine) SS
Aventyl
(Nortriptyline
Hydrochloride) SS

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				

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 - Initial or Prolonged Other	Chills Diarrhoea Drug Abuser	Health Professional Other	160 Mg (Oxycodone Hydrochloride)	PS		ORAL DAILY, ORAL	160 MG,	

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 Polysubstance Abuse	Health Professional Company Representative	Oxycontin Tablets (Oxycodone Hydrochloride)	PS			80 MG, SEE TEXT, ORAL ORAL RESPIRATORY (INHALATION) INHALATION	
		Ethanol (Ethanol) Marijuana (Cannabis) Cocaine (Cocaine)	SS SS 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

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Outcome	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Drug Tolerance							
Drug Withdrawal							
Convulsions	Consumer	Oxycontin Tablets					
Drug Withdrawal Syndrome	Health	(Oxycodone Hydrochloride)	PS			SEE TEXT	
Fatigue	Professional						
Gastroenteritis	Other	Heroin (Diamorphine)	SS				
Hallucination		Marijuana (Cannabis)	SS				
Headache		Roxicodone (Oxycodone Hydrochloride)	SS	ORAL	15 MG, ORAL		
Hyperhidrosis							
III-Defined Disorder							
Insomnia							
Irritability		Lorcet (Paracetamol, Hydrocodone Bitartrate)	SS				
Mood Swings							
Muscle Spasms							
Myalgia		Codeine (Codeine)	SS				

Nausea	Neurontin	C
Nervousness	Flexeril	C
Pain	Zoloft	C
Paranoia	Efexor	C
Polysubstance Abuse	Motrin	C
Suicidal Ideation	Percocet	C
Temperature Regulation Disorder	Medrol	C
Tremor		
Vomiting		
Weight Decreased		

Date:06/21/04ISR Number: 4399218-6Report Type:Periodic Company Report #USA-2004-0013094 Age:17 YR Gender:Female I/FU:I

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) 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) PS					
			Morphine Sulfate (Similar To Nda 19-516) SS					
			Hydrocodone Bitartrate (Similar To Ind 59,175) SS					
			Hydrocodone Bitartrate					SS

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Marijuana (Cannabis) SS
Cocaine (Cocaine) SS

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)	PS				
		Other	Crack Cocaine (Cocaine)	SS				

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					
		Other	(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	Consumer	Oxycontin Tablets					
		Other	(Oxycodone Hydrochloride)	PS		MG,		
			Marijuana (Cannabis)	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	Agitation	Study	Morphine Sulfate					
Other	Blood Alcohol Increased	Health	(Similar To Nda					
	Blood Alkaline	Professional	19-516) (Morphine Sulfate)	PS		ORAL	ORAL	
	Phosphatase Increased	Other	Benzodiazepine Derivatives ()	SS		ORAL	ORAL	
	Blood Pressure Systolic Increased		Acetaminophen W/Hydrocodone Bitartrate					
	Cerebrovascular Accident		(Paracetamol, Hydrocodone	SS		ORAL	ORAL	
	Coma		Ethanol (Ethanol)	SS		ORAL	ORAL	
	Convulsion		Acetylsalicylic Acid (Acetylsalicylic Acid)	SS		ORAL	ORAL	
	Drug Screen Positive		Marijuana (Cannabis)	SS		ORAL	ORAL	
	Heart Rate Decreased							
	Respiratory Rate Decreased							
	Respiratory Rate Increased							
	Somnolence							

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
Other	Drug Effect Decreased	Foreign

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Professional
Other

Product	Role	Manufacturer	Route	Dose	Duration
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	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Anger Anxiety Back Pain	Consumer Health Professional Other	Oxycontin Tablets(Oxycodone Hydrochloride) Cr Tablet Perocet (Oxycodonehydrochlor ide, Paracetamol)	PS		ORAL ORAL	5 MG, HS,	
	Bronchitis Acute Burning Sensation Carpal Tunnel Syndrome Cough Depression Suicidal Diabetic Neuropathy Drug Abuser Drug Dependence Drug Withdrawal Syndrome Hypoaesthesia Intervertebral Disc Degeneration Irritability Lethargy Nasopharyngitis Nervousness Osteoarthritis Pain Paraesthesia Polysubstance Abuse Self-Injurious Ideation Tremor		Lortab (Paracetamol, Hydrocodone Bitartrate) Marijuana (Cannabis) Restoril (Temazepam) Trazadone (Trazadone) Phenobarbital (Phenobarbital) Gliburide (Glibenclamide) Ativan (Lorazepam) Effexor (Venlafaxine Hydrochloride)	SS SS C C C C C C C C				

Outcome PT
 Hospitalization - Anxiety
 Initial or Prolonged Constipation
 Other Depression
 Drug Abuser
 Drug Dependence
 Drug Tolerance
 Drug Withdrawal Syndrome
 Fatigue
 Night Sweats
 Nodule

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Oedema Peripheral
 Pain
 Sleep Disorder
 Suicidal Ideation
 Weight Decreased
 Weight Increased

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Consumer	Ms Contin Tablets					
Other	(Morphine Sulfate)	PS		ORAL	60 MG, BID,	
	Cocaine (Cocaine)	SS		ORAL		
	Marijuana (Cannabis)	SS		SEE TEXT		
	Celebrex	C		SEE TEXT		
	Remeron	C				
	Prednisone	C				
	Arava	C				
	Elavil	C				
	Methotrexate	C				
	Folic Acid	C				
	Vistapril	C				
	Clonidine	C				
	Toradol	C				

Outcome PT
 Death Accidental Overdose
 Report Source Health
 Professional (Similar To Nda
 Other 19-516) (Morphine
 Sulfate) PS
 Marijuana (Cannabis) SS
 Ethanol (Ethanol) SS
 Nicotine (Nicotine) SS

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

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Depressed Level Of
Consciousness

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Drug Screen Positive		Study	Oxycontin Tablets					
Gastrointestinal		Health	(Oxycodone					
Haemorrhage		Professional	Hydrochloride) Cr					
Heart Rate Increased		Other	Tablet	PS		ORAL		ORAL
Hepatotoxicity			Benzodiazepine					
Hyperkalaemia			Derivatives	SS		ORAL		ORAL
Lethargy			Effexor (Venlafaxine					
Liver Function Test			Hydrochloride)	SS		ORAL		ORAL
Abnormal			Trazodone					
Occult Blood Positive			(Trazodone)	SS		ORAL		ORAL
Poisoning Deliberate			Valproic Acid					
Pyrexia			(Valproic Acid)	SS		ORAL		ORAL
Renal Failure			Marijuana (Cannabis)	SS				
Somnolence								
Transaminases Increased								

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 -	Anger	Consumer	Oxycontin Tablets					

Hyperpyrexia
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

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

White Blood Cell Count
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:09/07/04ISR Number: 4401272-XReport Type:Periodic Company Report #US-BRISTOL-MYERS SQUIBB COMPANY-12495263

Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Ineffective	Health	Coumadin	PS	Bristol-Myers Squibb			
	Drug Interaction	Professional		Company		ORAL	Dose	
	International Normalised						increased	
	Ratio Decreased						from 40	
							mg/week	
							starting on	
		Marijuana	I					

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 -	Agitation	Study	Oxycodone					
Initial or Prolonged	Apnoea	Health	Hydrochloride					
Other	Coma	Professional	(Similar To Nda					
	Drug Toxicity	Other	20-553)(Oxycodone					
	Drug Withdrawal Syndrome		Hydrochloride)	PS		ORAL	ORAL	
	Hypotonia		Benzodiazepine					
	Hypoventilation		Derivatives()	SS		ORAL	ORAL	
	Hypoxia		Carisoprodol					
	Laryngospasm		(Carisoprodol)	SS		ORAL	ORAL	
	Miosis		Aspirin W/Codeine					
	Multiple Drug Overdose		(Codeine Phosphate,					
	Polysubstance Abuse		Acetylsalicylic					
	Somnolence		Acid)	SS		ORAL	ORAL	
		Marijuana (Cannabis)	SS					
		Antipsychotics	C					

Trazodone
(Trazodone) C
Valproic Acid
(Valproic Acid) C

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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	Abdominal Pain	Literature	Acetaminophen					
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Health Professional	(Acetaminophen) Marijuana (Cannabis)	PS SS			15-25 GRAMS	
Other	Aspartate Aminotransferase Increased Blood Bicarbonate 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				(INHALATION)	RESPIRATORY INHALATION		

Date:10/21/04ISR Number: 4483619-1Report Type:Expedited (15-DaCompany Report #2004AL000901

Age:29 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Multiple Drug Overdose	Literature	Children'S Apap Elixir (Acetaminophen) (Alpharma)	PS	Alpharma			
			Infants' Apap Drops (Acetaminophen) (Alpharma)	SS	Alpharma			
			Marijuana	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 Coronary Artery	Consumer Health	Oxycontin Tablets(Oxycodone Hydrochloride) Cr	PS		MG		
	Blood Ethanol Increased	Professional	Hydrocodone	SS		MG		
	Bronchopneumonia	Other	Tablet	PS				
	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		

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Marijuana (Cannabis) SS
Oxazepam (Oxazepam) SS
Temazepam
(Temazepam) SS
Ephedrine
(Ephedrine) SS
Pseudoephedrine
(Pseudoephedrine) SS

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	Head Injury	Other	Oxycodone	PS				
	Poisoning		Morphine(Morphine)	SS				
Other	Polysubstance Abuse		Valium (Diazepam)	SS				
	Road Traffic Accident		Marijuana (Cannabis)	SS				
			Lidocaine					
			(Lidocaine)	SS				
			Tylenol(Paracetamol)	SS				
			Hydrocodone(Hydrocodone)	SS				

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 - Initial or Prolonged	Drug Toxicity	Other	Oxycodone					
	Head Injury		Hydrochloride					
Other	Polysubstance Abuse		(Similar To Nda					
	Road Traffic Accident		20-553) (Oxycodone					

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					

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: 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					

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

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 Drug Abuser Multiple Drug Overdose Intentional	Literature	Cocaine Hcl Topical Solution, 10%					
		(Cocaine)	PS					
		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	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Agitation	Study Health	Oxycodone Hydrochloride					
	Depressed Level Of Consciousness	Professional Other	(Similar To Nda 20-553) (Oxycodone Hydrochloride)	PS		ORAL	ORAL	
	Drug Effect Decreased Drug Screen Positive		Morphine Sulfate (Similar To Nda 19-516) (Morphine Sulfate)	SS		ORAL	ORAL	
	Electrocardiogram Qrs Complex Prolonged		Amitriptyline (Amitriptyline)	SS		ORAL	ORAL	
	Heart Rate Increased Multiple Drug Overdose		Cyclobenzaprine	SS		ORAL	ORAL	
	Respiration Abnormal Treatment Noncompliance	(Cyclobenzaprine) Cocaine (Cocaine) Marijuana (Cannabis) Barbiturates ()	SS SS SS SS			ORAL ORAL	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:12/15/04ISR Number: 4530403-6Report Type:Expedited (15-DaCompany Report #USA-2002-0002836

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

Outcome	PT
Death Hospitalization - Initial or Prolonged Other	Alcohol Withdrawal Syndrome Alcoholism Anxiety Back Pain Completed Suicide Cough Dependent Personality Disorder Depression Drug Abuser Drug Dependence

Freedom Of Information (FOI) Report

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Drug Ineffective								
Drug Withdrawal Syndrome								
Gun Shot Wound								
Hypoaesthesia		Consumer	Oxycontin Tablets 20					
Impaired Driving Ability		Health	Mg (Oxycodone					
Inadequate Analgesia		Professional	Hydrochloride)Cr					
Intentional Drug Misuse		Other	Tablet PS		ORAL	SEE IMAGE		
Loss Of Consciousness			Lorcet (Paracetamol,					
Muscle Spasms			Hydrocodone					
Musculoskeletal Stiffness			Bitartrate) SS			10 MG		
Neck Pain			Marijuana (Cannabis) SS					
Oxygen Saturation			Remeron					
Decreased			(Mirtazapine) C					
Pain			Relafen (Nabumetone) C					
Pain In Extremity			Neurontin					
Paraesthesia			(Gabapentin) C					
Personality Disorder			Ultram C					
Polysubstance Abuse			Soma (Carisoprodol) C					
Pyrexia			Effexor (Venlafaxine					
Rhonchi			Hydrochloride) C					
Somatoform Disorder			Biaxin					
Temperature Intolerance			(Clarithromycin) C					
Upper Respiratory Tract			Xanax (Alprazolam) C					
Infection			Zanaflex (Tizanidine					
Weight Decreased			Hydrochloride) C					
Wheezing			Tranxene					
			(Clorazepate					
			Dipotassium) C					
			Zoloft (Sertraline					
			Hydrochloride) C					

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:01/05/05ISR Number: 4546668-0Report Type:Expedited (15-DaCompany Report #2004AL000901

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

Outcome	PT
Death	Abdominal Pain
Hospitalization -	Alanine Aminotransferase

Initial or Prolonged Increased
 Aspartate
 Aminotransferase
 Increased
 Blood Bicarbonate
 Decreased
 Blood Creatinine

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Increased
 Blood Ph Decreased
 Bradycardia
 Brain Herniation
 Completed Suicide
 Confusional State
 Drug Screen Positive
 Encephalopathy
 Fatigue
 Haematocrit Increased
 Hypertension
 International Normalised
 Ratio Increased
 Nausea
 Oral Intake Reduced
 Overdose
 Urine Output Decreased

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Literature	Children'S Apap					
Health	Elixir					
Professional	(Acetaminophen)					
	(Alpharma)	PS	Alpharma			
	Infants' Apap Drops					
	(Acetaminophen)					
	(Alpharma)	SS	Alpharma			
	Marijuana	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,	
						ORAL		
			Marijuana (Cannabis)	SS		RESPIRATORY		
						(INHALATION)	INHALATION	

Unknown C

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: Novartis Sector: Pharma 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		Omeprazole	C	UNKNOWN UNKNOWN		20 mg/d	

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Prednisolone	C	UNKNOWN	5 mg/d
Clonazepam	I	UNKNOWN	

Date:02/10/05ISR Number: 4579586-2Report Type:Expedited (15-DaCompany Report #2004AL000912

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anoxic Encephalopathy	Literature	Diazepam Tablets					
Hospitalization - Initial or Prolonged	Coma Drug Abuser Drug Toxicity Heart Rate Increased Lung Consolidation Multiple Drug Overdose Subarachnoid Haemorrhage Therapy Non-Responder Ventricular Fibrillation		Usp, 10 Mg (Purepac) Oxycodone (Long-Acting) Amphetamine Marijuana	PS SS SS	Purepac	ORAL	PO	
				SS		ORAL	PO	
				SS		ORAL	PO	

Date:02/10/05ISR Number: 4579915-XReport Type:Expedited (15-DaCompany Report #2004AL000679

Age:47 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Blood Pressure Systolic Decreased Completed Suicide Confusional State Multiple Drug Overdose Renal Failure Acute	Literature Health Professional	Clonazepam Tablets Usp, 2 Mg (Purepac) Alprazolam Tablets Usp, 2 Mg (Purepac) Amitriptyline Marijuana	PS SS SS	Purepac	ORAL	PO	
				SS		ORAL	PO	
				SS		RESPIRATORY		

Rhabdomyolysis
Somnolence
Tachycardia

(INHALATION) INH

Date:02/10/05ISR Number: 4579931-8Report Type:Expedited (15-DaCompany Report #2004AL000713

Age:26 YR Gender:Female I/FU:F

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

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Electrolyte Imbalance							
Glucose Urine Present							
Haematuria	Literature	Clonidine					
Haemodialysis	Health	Hydrochloride					
Haemorrhage	Professional	Tablets Usp, 0.3 Mg					
Heart Rate Decreased		(Purepac)	PS	Purepac	ORAL		PO
Hyperglycaemia		Venlafaxine	SS		ORAL		PO
Hypotension		Mirtazapine	SS		ORAL		PO
Hypoxia		Marijuana	SS				
Hypoxic Encephalopathy		Charcoal, Activated	SS				
International Normalised		Cocaine	SS				
Ratio Increased		Amphetamine	C				
Multi-Organ Failure							
Multiple Drug Overdose							
Mydriasis							
Myocardial Infarction							
Papillary Muscle							
Haemorrhage							

Proteinuria
Prothrombin Time
Prolonged
Pupil Fixed
Sinus Tachycardia
Supraventricular
Tachycardia
Troponin Increased
Ventricular Fibrillation
Ventricular Tachycardia
White Blood Cell Count
Decreased

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
Death Alcohol Withdrawal
Hospitalization - Syndrome
Initial or Prolonged Anxiety
Other Back Pain
Completed Suicide
Depression
Drug Abuser
Drug Dependence
Drug Ineffective
Drug Withdrawal Syndrome
Gun Shot Wound
Hypoaesthesia
Impaired Driving Ability
Inadequate Analgesia
Intentional Drug Misuse
Loss Of Consciousness
Muscle Spasms
Musculoskeletal Stiffness
Neck Pain
Pain
Pain In Extremity
Paraesthesia
Polysubstance Abuse
Rhonchi
Temperature Intolerance

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Upper Respiratory Tract
Infection

Weight Decreased	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Wheezing	Consumer	Oxycontin					
	Health Professional	(Oxycodone Hydrochloride) Cr	PS		ORAL	SEE IMAGE,	

Other

ORAL

Lorcet (Paracetamol,
Hydrocodone
Bitartrate) SS 10 MG
Marijuana (Cannabis) SS SEE TEXT
Remeron
(Mirtazapine) C
Relafen (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
Depotassium) C
Zoloft (Sertraline
Hydrochloride) C

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 -	Anxiety	Consumer	Oxycontin Tablets					
Initial or Prolonged	Back Pain	Health	(Oxycodone					
Other	Cold Sweat	Professional	Hydrochloride)Cr					
	Confusional State	Other	Tablet	PS		ORAL	20 MG, BID,	
	Delusion					ORAL		
	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							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

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) Cocaine (Cocaine)	PS SS			ORAL PO RESPIRATORY (INHALATION) INH		
		Marijuana (Cannabis)	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 Other	Abdominal Pain Alcoholism Anxiety	Upper Health Professional Other	Oxycontin (Oxycodone Hydrochloride) Cr Tablet					
	Arthralgia Depression Drug Abuser Drug Dependence Drug Screen Positive Drug Withdrawal Syndrome Emotional Distress Gastritis Headache Injury Insomnia Mental Disorder Nausea Pain Polysubstance Dependence Sick Cell Anaemia With Crisis Vomiting	Consumer Health Professional Other	Demerol (Pethidine Hydrochloride) SS Dilaudid (Hydromorphone Hydrochloride) SS Cocaine (Cocaine) SS Alcohol (Ethanol) SS 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			INTRAVENOUS INTRAVENOUS INTRAVENOUS INTRAVENOUS INTRAVENOUS INTRAVENOUS ORAL ORAL	12, DAILY,	

Celebrex (Celecoxib) C
Zantac (Ranitidine
Hydrochloride) C

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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	Oxycodone Hydrochloride (Similar To Nda 20-553) (Oxycodone Hydrochloride)	PS		ORAL	ORAL	
Drug Abuser Fall	Heart Rate Increased Multiple Drug Overdose Skin Laceration	Professional Other	Acetaminophen W/Oxycodone/Paraceta mol, Oxycodone Hydrochloride)	SS	ORAL	ORAL		
			Carisoprodol (Carisoprodol)	SS	ORAL	ORAL		
			Ethanol (Ethanol) Benzodiazepine Derivatives	SS	ORAL	ORAL		
			Marijuana (Cannabis)	SS				

Date:03/16/05ISR Number: 4618043-1Report Type:Periodic Company Report #S04-USA-06047-01 Age:17 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Joint Injury Muscle Spasms Night Sweats Suicidal Ideation Suicide Attempt Upper Limb Fracture	Health Professional	Lexapro (Escitalopram) Marijuana	PS SS		ORAL	10 MG QD PO	

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 - Initial or Prolonged	Blood Calcium Decreased Crying	Study Health	Oxycontin Tablets (Oxycodone					

Other	Intentional Drug Misuse	Professional	Hydrochloride) Cr				
	Multiple Drug Overdose	Other	Tablet	PS	RESPIRATORY	(INHALATION)	SEE IMAGE
	Intentional						
	Polysubstance Abuse		Acetaminophen				
	Suicidal Ideation		(Paracetamol)	SS	ORAL		SEE TEXT
	Tachycardia		Marijuana (Cannabis)	SS	RESPIRATORY	(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
 Death Alcohol Withdrawal
 Hospitalization - Syndrome
 Initial or Prolonged Anxiety
 Other Arthralgia
 Completed Suicide
 Depression

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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 Tablets 20					
Drug Ineffective	Health	Mg(Oxycodone					
Drug Withdrawal Syndrome	Professional	Hydrochloride) Cr					
Gun Shot Wound	Other	Tablet	PS		ORAL	20 MG, BID,	
Hypoaesthesia					ORAL		
Impaired Driving Ability		Lorcet (Paracetamol,					
Inadequate Analgesia		Hydrocodone					
Loss Of Consciousness		Bitartrate) Unknown	SS		ORAL	10 MG, SEE	
Muscle Spasms					TEXT, ORAL		
Musculoskeletal Stiffness		Marijuana (Cannabis)	SS		ORAL	40 MG, SEE	
Pain					TEXT, ORAL		
Pain In Extremity		Remeron					
Paraesthesia		(Mirtazapine)	C				
Polysubstance Abuse		Relafen (Nabumetone)	C				
Suicidal Ideation		Neurontin					
Temperature Intolerance		(Gabapentin)	C				
Upper Respiratory Tract Infection		Ultram	C				
Weight Decreased		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
 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
 Nasopharyngitis
 Pain
 Polysubstance Abuse
 Pseudarthrosis
 Radicular Pain
 Self-Injurious Ideation

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Tremor

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Consumer Health Professional Other	Oxycontin Tablets (Oxycodone Hydrochloride) Cr Tablet PS			ORAL		
	Percocet (Oxycodone Hydrochloride, Paracetamol)	SS		ORAL ORAL	5 MG, HS,	
	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:04/18/05ISR 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:	ORAL	250 mg, QD	91 DAY
			Marijuana	SS	Novartis Sector:			
			Lamisil	SS	Novartis Sector:	ORAL	250 mg, QD	
			Celexa	C		ORAL	30 mg, QD	
			Neurontin	C		ORAL		

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 Health	Morphine Sulfate (Similar To Nda					
Other	Lethargy	Professional	19-516) (Morphine Sulfate) Unknown	PS		ORAL	ORAL	
	Loss Of Consciousness	Other	Ethanol (Ethanol)	SS		ORAL	ORAL	
	Overdose		Cocaine (Cocaine)	SS		RESPIRATORY		
	Oxygen Saturation Decreased		Marijuana (Cannabis)	SS		(INHALATION)	INHALATION	
	Polysubstance Abuse							
	Respiratory Rate Decreased							
	White Blood Cell Count Increased							

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

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
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Hospitalization - Pneumothorax Clozaril PS Novartis Sector:
 Initial or Prolonged Marijuana SS Pharma ORAL 300 mg/d

Date:05/04/05ISR Number: 4653724-5Report Type:Expedited (15-DaCompany Report #KII-2005-0016206 Age:37 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Alcohol Use Apnoea Blood Glucose Increased Blood Ph Decreased Blood Pressure Decreased Coma Drug Abuser Electrocardiogram Qrs Complex Prolonged Electrocardiogram Qt Corrected Interval Prolonged Loss Of Consciousness Multiple Drug Overdose Somnolence	Study Health Professional Other	Oxycontin Tablets (Oxycodone Hydrochloride) Cr Tablet Acetaminophen W/Oxycodone (Paracetamol, Oxycodone Hydrochloride) Aspirin With Carisoprodol () Diphenhydramine (Diphenhydramine) Antipsychotics() Alcohol (Ethanol) Marijuana (Cannabis)	PS SS SS SS SS	Novartis Sector: Pharma	ORAL ORAL ORAL ORAL ORAL ORAL ORAL ORAL	300 mg/d	

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 Marijuana Lamisil C C	PS SS SS	Novartis Sector: Pharma Novartis Sector: Pharma	ORAL ORAL ORAL ORAL	250 mg, QD 250 mg, QD 30 mg, QD	91 DAY

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 Tablet Alcohol (Ethanol) Marijuana (Cannabis)	PS SS SS				

Date:05/19/05ISR Number: 4666065-7Report Type:Expedited (15-DaCompany Report #PHEH2005US04277 Age:42 YR Gender:Male I/FU:F

Outcome	PT
Other	Blood Cannabinoids

Increased

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Blood Creatinine
Increased

Laboratory Test Abnormal	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Lamisil	PS Novartis Sector: Pharma	ORAL		250 mg, QD	91 DAY	
	Marijuana Lamisil	SS SS Novartis Sector: 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	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Alcoholism Anxiety Back Pain	Consumer Health Professional Other	Oxycontin Tablets(Oxycodone Hydrochloride) Cr Tablet	PS		ORAL ORAL; 20 M G, TID	20 MG, BID,	
	Cervicobrachial Syndrome Cold Sweat Confusional State Delusion Depressed Mood Depression Disturbance In Attention Drug Abuser Drug Dependence Drug Ineffective Drug Withdrawal Syndrome Hallucination, Auditory Insomnia Major Depression Malaise Memory Impairment Muscle Spasms Muscle Twitching Pain Paranoia Psychotic Disorder Schizophrenia, Paranoid Type Tremor Weight Decreased Weight Increased	Alcohol (Ethanol) Marijuana(Cannabis) Cocaine(Cocaine) Vicodin(Paracetamol, Hydrocodone Bitartrate) Tablet Norco Xanax (Alprazolam)	SS SS SS SS C C					

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 Hydromorphone Hcl (Similar To Nda 21-044)(Hydromorphon e Hydrochloride) SS Gamma Hydroxybutyrate And			ORAL ORAL		

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Analog	SS	ORAL	ORAL
Barbiturates	SS		
Benzodiazepine			
Derivatives	SS		
Marijuana (Cannabis)	SS		
Cocaine (Cocaine)	SS		

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Back Pain Cervicobrachial Syndrome Cold Sweat	Consumer Health Professional Other	Oxycontin Tablets(Oxycodone Hydrochloride) Cr Tablet PS Alcohol (Ethanol) SS Marijuana (Cannabis) SS Cocaine (Cocaine) SS Vicodin (Paracetamol, Hydrocodone Bitartrate) C Norco C Xanax (Alprazolam) C			ORAL SEE IMAGE		
	Delusion 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							

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							

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

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 -	Anoxic Encephalopathy	Study	Morphine Sulfate					
Initial or Prolonged	Blood Creatinine	Health	(Similar To Nda					
Other	Increased	Professional	19-516) (Morphine					
	Blood Electrolytes	Other	Sulfate) Unknown	PS				
	Abnormal		Methadone					
	Cardiac Arrest		(Methadone)	SS				
	Neurological Examination		Cocaine (Cocaine)	SS				
	Abnormal		Marijuana (Cannabis)	SS				
	Polysubstance Abuse		Antiepileptics()	SS				
	Rhabdomyolysis		Benzodiazepine					
	Toxicologic Test Abnormal		Derivatives()	SS				
	Troponin Increased		Ssri()	SS				
	Urine Output Decreased							

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	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Acute Pulmonary Oedema	Literature	Cocaine (Cocaine)	PS				
	Drug Toxicity		Oxycodone					
	Intentional Drug Misuse		(Oxycodone)	SS				
	Overdose		Meprobamate					
	Polysubstance Abuse		(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				

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Summary report for FOI selections:

Selection by inexact search of active ingredient:
MARIJUANA%

Selection by inexact search of Tradename/Verbatim:
MARIJUANA%

Total number of reports: 342

From: 01-NOV-1997 To: 30-JUN-2005