Project On Government Oversight

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October 25, 2010

The Honorable Margaret A. Hamburg Commissioner U.S. Food and Drug Administration White Oak Building 1 10903 New Hampshire Avenue Silver Spring, MD 20993

Via: E-mail margaret.hamburg@fda.hhs.gov

Dear Commissioner Hamburg:

The Project On Government Oversight is an independent, nonprofit organization that provides oversight of the federal government. We take a keen interest in the U.S. Food and Drug Administration (FDA), which receives around \$4 billion a year in federal taxpayer dollars to regulate almost twenty-five percent of the U.S. economy.

We would like to bring to your attention a potentially dangerous interaction of the drugs Seroquel (quetiapine) and methadone that may be putting veterans at risk. According to news accounts, these drugs are now widely used in combination to treat veterans with Post-Traumatic Stress Disorder (PTSD). However, a study published in 2007, and funded by Seroquel's maker, AstraZeneca, found that Seroquel significantly increases plasma levels of methadone. This may increase the risk of a methadone overdose.

Further, between 2002 and July 2010, the FDA's Adverse Event Reporting System (AERS) received over eighty reports of patients who overdosed and often died while taking Seroquel in combination with methadone. As I'm sure you are aware, AERS reports are known to underestimate the true number of drug adverse events, so POGO is alarmed that so many reports have been filed with the FDA on Seroquel and methadone interactions.

However, despite the known interaction effect, the FDA-approved labels for Seroquel and methadone do not note the study from 2007, and the labels do not discuss this interaction in the warning section. In the interest of patients, and especially veterans, we ask that you make changes to both labels to note this drug interaction. Further, we ask that you immediately issue an alert to inform patients and prescribers.

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BACKGROUND

The dangers of Seroquel and methadone were first reported in a study published in 2007 in the *Journal of Clinical Psychopharmacology*. This study found that Seroquel significantly increases blood plasma levels of methadone. In one patient, Seroquel led to an 85 percent increase in blood plasma levels of methadone. The study found wide variability across patients, which the authors argue may be due to differences in genetic subpopulations.

Yet, prescriptions of Seroquel and methadone are at an all time high for veterans. An investigation by the *Military Times* found that military spending on Seroquel almost quadrupled between 2001 and 2009.²

Many of these veterans are also taking methadone for pain relief and to control anxiety caused by PTSD. The *Military Times* found that methadone overdose has caused at least sixty death deaths in the military, more than any other drug—legal or illegal.³

A separate investigation by the *Associated Press* noted that military expenditures on Seroquel have jumped sevenfold since the beginning of the war in Afghanistan.⁴ The military spent \$8.6 million on Seroquel last year alone.⁵ Physicians said that they are prescribing it to provide relief from nightmares and anxiety caused by PTSD. The *Associated Press* also discovered that Seroquel has become the Department of Veterans Affairs' (VA) second biggest drug expenditure since 2007. Last year the VA spent \$125 million on Seroquel compared to \$14.4 million in 2001.⁶

In the case of one soldier, Andrew White, the *Associated Press* reported that the interaction of Seroquel and methadone may have been deadly. To treat his PTSD, he was prescribed Seroquel, methadone, and Paxil. Mr. White's autopsy report stated, "The narcotic analgesic methadone was present in the blood at a concentration that can cause fatal respiratory depression in those who do not have adequate tolerance to opioid medications."

Again, POGO urges FDA to improve the labels of Seroquel and methadone to note the 2007 study in the *Journal of Clinical Psychopharmacology*. Further, we ask FDA to issue an alert to inform patients and prescribers. We also have concerns about the quality of the data in the AERS

¹ Claude Uehlinger et al., "Increased (R)-Methadone Plasma Concentrations by Quetiapine in Cytochrome P450s and ABCB1 Genotyped Patients," *Journal of Clinical Psychopharmacology*, June 3, 2007. http://www.ncbi.nlm.nih.gov/pubmed/17502774 (Downloaded October 22, 2010)

² Andrew Tilghman and Brendan McGarry, "Medicating the Military: Use of Psychiatric Drugs has Spiked; Concerns Surface about Suicide, other Dangers," *Army Times*, March 17, 2010.

http://www.armytimes.com/news/2010/03/military_psychiatric_drugs_031710w/ (Downloaded October 22, 2010) ³ Andrew Tilghman and Brendan McGarry, "Rx for Death: Troop Deaths Soar with Prescriptions for War

Wounded," *Navy Times*, September 7, 2010. http://www.navytimes.com/news/2010/09/military-wounded-prescriptions-troop-deaths-soar-080910/ (Downloaded October 22, 2010)

⁴ Matthew Perrone, "Questions Loom over Drug Given to Sleepless Vets," *Associated Press*, August 30, 2010.

⁴ Matthew Perrone, "Questions Loom over Drug Given to Sleepless Vets," *Associated Press*, August 30, 2010. http://news.yahoo.com/s/ap/20100830/ap_on_he_me/us_veterans_sleep_drug (Downloaded October 22, 2010) (Hereinafter Perrone, "Questions Loom")

⁵ Perrone, "Questions Loom."

⁶ Perrone, "Questions Loom."

⁷ Perrone, "Questions Loom."

database and how the FDA uses this information to monitor for adverse drug events. To help answer our concerns, we ask that FDA provide someone to brief our staff.

We have attached a copy of the 2007 study in the *Journal of Clinical Psychopharmacology* and copies of the FDA's AERS reports noting an adverse reaction to Seroquel and methadone.

I appreciate your review of this letter and the attached documents. If you have any questions, please do not hesitate to contact Paul Thacker at (202) 347-1122 or thacker@pogo.org.

Sincerely,

Danielle Brian
Executive Director

Paul D. Thacker Investigator

Enclosures: 2

cc: Senator Carl Levin

Chairman, Senate Armed Services Committee

Senator John McCain

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Ranking Member, Senate Armed Services Committee

Senator Daniel K. Akaka

Chairman, Senate Veterans' Affairs Committee

Senator Richard Burr

Ranking Member, Senate Veterans' Affairs Committee

The Honorable Eric K. Shinseki

Secretary

Department of Veterans Affairs

George Peach Taylor Jr., M.D., MPH

Acting Assistant Secretary of Defense for Health Affairs

Department of Defense

Study published in 2007 in the Journal of Clinical Psychopharmacology

Increased (R)-Methadone Plasma Concentrations by Quetiapine in Cytochrome P450s and ABCB1 **Genotyped Patients**

Claude Uehlinger, MD,* Séverine Crettol,† Philippe Chassot,* Murielle Brocard,† Liliane Koeb,† Marlyse Brawand-Amey,† and Chin B. Eap, PhD†

Abstract: Steady-state plasma concentrations of (R)- (ie, the active form), (S)-, and (R,S)-methadone were measured in 14 addict patients in methadone maintenance treatment, before and after introduction of quetiapine, administered at a mean dosage of 138 mg/d (SD, 87 mg/d; median, 125 mg/d; range, 50-300 mg/d) during a mean period of 30 days (SD, 8 days; median, 30 days; range, 20-48 days). Eleven patients were genotyped as being CYP2D6 extensive metabolizers (EMs) and 3 patients as poor metabolizers. Eleven patients had the ABCB1 3435 CT or CC genotypes, and 3 patients had the ABCB1 3435 TT genotype, the latter genotype being associated with lower P-glycoprotein activity. Quetiapine significantly increases (R)-methadone concentration-dose ratios in the whole group [increase for (R)-methadone: mean, +21%; SD, +28%; median, +13%; range, -23% to +85%; P = 0.026], but not for (S)-methadone (mean, +23%; SD, +43%; median, +6%; range, -30% to +115%; P = 0.12) or for (R,S)-methadone (mean, +21%; SD, +34%; median, +9%; range, -21% to +95%; P = 0.064). The mean increases of (R)-methadone concentration-dose ratios were of 7%, 21%, and 30% in the CYP2D6 poor metabolizers, heterozygous EMs, and homozygous EMs, respectively, whereas they were of 3%, 23%, and 33% in the subjects with the ABCB1 3435 TT, CT, and CC genotypes, respectively. Thus, quetiapine increases the plasma concentrations of (R)-methadone, possibly in part by an interaction with CYP2D6 and/or with the P-glycoprotein transporter system. No signs of overmedication caused by increased methadone plasma concentrations were noticed by the staff or reported by the patients.

(J Clin Psychopharmacol 2007;27:273-278)

ethadone is metabolized by several isoforms of the ethadone is metabolized by several isolothis of the cytochrome P450 (CYP) family, mainly CYP3A4 and CYP2B6, and to a lesser extent by CYP2D6.¹⁻⁵ Psychiatric

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comorbidity is highly prevalent among drug abusers,6 and antidepressants and/or antipsychotics are commonly prescribed to patients in methadone maintenance treatment (MMT). We conducted several studies examining the in vivo influence of coadministrations of psychotropic drugs on the plasma levels of methadone in patients in MMT. We have thus previously shown that fluoxetine and fluvoxamine, 2 antidepressants of the selective serotonin reuptake inhibitor class, significantly increase the concentrations of methadone. 7,8 Interestingly, whereas fluvoxamine increased the concentrations of both enantiomers of methadone [ie, (R)-methadone or levomethadone, the active enantiomer, and (S)-methadone or dextromethadone, the inactive enantiomer], only (R)-methadone concentrations were increased by the addition of fluoxetine. This suggested that CYP2D6, which is strongly inhibited by fluoxetine, is preferentially involved in the metabolism of the (R)-enantiomer, whereas CYP3A4, which is inhibited by fluvoxamine, does not display any stereoselective activity toward methadone. A stereoselectivity of CYP2D6 toward (R)-methadone was also suggested by a subsequent study measuring the in vivo influence of paroxetine, another strong inhibitor of CYP2D6.9 Thus, whereas in 8 patients in MMT genotyped as being extensive metabolizers (EMs) of CYP2D6, paroxetine increased the plasma concentrations of both enantiomers of methadone, possibly by a strong inhibition of CYP2D6 and a mild inhibition of CYP3A4, in the 2 patients genotyped as being CYP2D6 poor metabolizers (PMs), (S)-methadone, but not (R)-methadone, was increased by paroxetine administration.3

Quetiapine is an atypical antipsychotic drug that is metabolized mainly by CYP3A4, but a small contribution of CYP2D6, for the 7-hydroxylation pathway, can be expected. 11 Quetiapine and several of its metabolites have no effect on the in vitro activity of CYP1A2, CYP2C9, CYP2D6, and CYP3A4 at clinically relevant concentrations12 (AstraZeneca, data in file). However, the inhibitory potential toward CYP enzymes has not been tested for all metabolites of quetiapine, and the inhibitory effect of quetiapine and/or of its metabolites toward CYP2B6 has not been tested either. In addition, both quetiapine and methadone are substrates of the efflux transporter permeability glycoprotein (PGP) encoded by the ABCB1 gene, 13-15 and interactions through this transporter system are also possible. We therefore examined whether the prescription of quetiapine to MMT patients could result in modified methadone plasma concentrations.

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As any interaction with methadone metabolism and/or transport by quetiapine, through an inhibition of CYP isozymes and/or PGP activities, is dependent on the CYP and ABCB1 genotypes, patients were genotyped for CYP3A5, CYP2B6, CYP2D6, and ABCB1 (no genotyping was done on CYP3A4 because genotyping this isozyme poorly reflects its activity¹⁶).

PATIENTS AND METHODS

This study was performed in Fribourg, and the corresponding ethics committee approved the protocol of the study (including the genetic analyses). The study was proposed to male and female addict patients (>18 and <65 years) in methadone maintenance therapy who were about to start an antipsychotic therapy with quetiapine. Patients had to be treated with methadone for at least 1 month, with an unchanged dose for at least 1 week. Exclusion criteria included a known sensibility to quetiapine, pregnant or breast-feeding women (a pregnancy test was carried out in all women of child-bearing age), introduction of a new comedication for less than 1 week before the inclusion, or change of the dose of the comedication within the last week before inclusion. Doses of quetiapine (immediate-release form, twice a day) were variable and chosen by the physician in charge of the patients, depending on the clinical state of the patients and independently from the study. Patients had to give their written informed consent to participate in the study. Twenty patients were included, but 5 subjects dropped out before the second blood sampling. A sixth patient was removed from further data analysis as the blood sample drawn after quetiapine treatment revealed undetectable quetiapine plasma levels, suggesting noncompliance. For each patient, the first blood sample was taken before the introduction of quetiapine, at least 5 days after any change of methadone dose (days with methadone dose kept unchanged: mean, 168 days; SD, 195 days; median, 81 days; range, 6-604 days) and at least 1 week after any changes of comedications. The second blood sample was taken after at least a 7-day treatment with quetiapine. Blood samples were taken at trough, just before the next methadone intake.

One patient had no comedications, and the 13 remaining patients were taking other drugs, none of which, with 1 exception, were known to be inducers or strong inhibitors of CYP enzymes [bromazepam (1 patient), (R,S)-citalopram (5 patients), escitalopram (1 patient), clonazepam (2 patients), clorazepate (1 patient), olanzapine (1 patient), trimipramine (1 patient), zolpidem (4 patients), and zopiclone (10 patients)]. One patient had paroxetine (20 mg/d) as comedication, a strong CYP2D6 inhibitor, but this treatment was maintained at constant dosage during the study. In all but 2 patients, the comedications were kept constant between the 2 blood samplings. In 1 patient, between the 2 blood samplings, citalopram dose was increased from 20 to 60 mg/d, zopiclone (7.5 mg/d) was withdrawn, and biperiden (4 mg/d) and zolpidem (10 mg/d) were introduced. In another patient, (R,S)-citalopram (40 mg/d) was replaced by escitalopram (20 mg/d), zolpidem (30 mg/d) was interrupted, and bromazepam (30 mg/d) and chloral hydrate (500 mg/d) were introduced. As none of these changes of comedications were expected to influence methadone plasma levels, and as similar results were obtained when removing the data of these 2 patients (data not shown), their data were kept for the final analysis. Two of the 14 patients had methadone doses modified between the 2 blood samplings, and methadone plasma levels—dose ratios were therefore used for statistical calculations for all patients. Urea and creatinine levels were within normal values in all patients, whereas hepatic functions were either normal or slightly disturbed (values of γ -glutamyltransferase, alanine aminotransferase, and/or aspartate amino transferase less than 3-fold the reference range) in 13 patients and moderately disturbed in 1 patient (values <6-fold the reference range).

(R)- and (S)-methadone plasma concentrations were measured by high-performance liquid chromatographymass spectrometry as previously described.2 The concentrations of quetiapine were determined using a high-pressure liquid chromatography column (analytical column: EC 125/2 Nucleosil 100-5 C18, 5- μ m silica gel, 125 × 2 mm; Astec, Basel, Switzerland) with a mass spectrometry detector (HP 1100 series; Agilent Technologies, Palo Alto, Calif) after a liquid-liquid extraction step. The LC conditions were as follows: mobile phase, 35% tetrahydrofuran-65% 4 mmol/L NH₄NO₃-1.5% methanol; flow rate, 0.3 mL/min. Analyses were performed in the selected-ion monitoring mode for the ions at m/z 384.2. The limit of quantification was 0.4 ng/mL. Intraday and interday coefficients of variation determined at 3 concentrations ranged from 0.9% to 1.8% (unpublished method, detailed method available on request).

Genotyping of CYP2D6 was performed by real-time polymerase chain reaction with the use of 5'-nuclease allelic discrimination assays (alleles *3, *4, *6; ABI PRISM 7000 Sequence Detection System; Applied Biosystems, Rotkreuz, Switzerland), and as previously described for the allele *5 and *XN. 17,18 Genotyping of CYP3A5 (allele *3), 16 CYP2B6 (alleles *4, *5, *6, *7, *9), and ABCB1 (3435C>T)19 was performed as previously described. The Wilcoxon matched paired test was used to compare the concentrations of methadone measured before and after introduction of quetiapine, and the Mann-Whitney U test was used to compare different quetiapine and methadone plasma levels between different CYP or ABCB1 genotypes (Statistica Release 4.5, Statsoft; Loll & Nielsen, Hamburg, Germany). A P value lower than 0.05 was considered as statistically significant. In the original protocol, it was planned to include 15 patients. Based on previously published mean and SDs of methadone plasma concentrations, 20 a sample size of 15 would achieve 80% power to detect a difference of 32% in the mean concentration of methadone with a significance level (α) of 0.05.

RESULTS

Fourteen patients were finally included in the study (all were white and smokers; 11 men). The mean age of the patients was 34 years (SD, 8 years; median, 35 years; range, 23–46 years), and the mean weight was 71 kg (SD, 14 kg; median, 72 kg; range, 44–96 kg). The mean duration of

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The P values for changes of (R)-, (S)-, and (R,S)-methadone concentration-dose ratios after quetiapine administration are given. EM indicates extensive metabolizer, IM, intermediate metabolizer, PH, poor metabolizer.

TABLE 1. (R)-Methadone, (S)-Methadone, and (R,S)-Methadone Concentration-Dose Ratios Before and After the Introduction of Quetiapine (Mean Dosage,

	Quetiapine Plasma	Concentrations, ng/mL	33	34	15	19	13	٣	16	16	183	160	108	36	31	42	50.89	56.94	1
		1	*1/#5	L*/I*	9*/1*	I_{*}/I_{*}	I_*/I_*	9*/9*	\$*//*	*1/*5	I_*/I_*	9*//*	9*/1*	I_*/I_*	9*/9*	I_*/I_*	l		1
		3435C>1 CYF1B0 Genotype Genotype	CT	CL	ပ္ပ	CI	ပ္ပ	CL	CI	11	ပ္ပ	TT	TT	CT	CI	CT	1	i	1
		CYP2D6 genotype	EM	EM	PM	PM	Μ	EM	PM	M	M	M	M	EM	M	M	l	I	1
	Change of (R,S)-Methadone	After Quetiapine, %	2	95	0	73	48	13	-20	19	47	3	-21	7	9	33	21.38	33.83	0.064
	(R,S)-Methadone Before	After Quetiapine, Quetiapine, $\%$ ng \times d/mL \times mg	2.89	3.04	2.94	4.42	1.87	4.30	4.17	2.29	3.10	7.60	8.12	2.40	4.62	2.11	3.85	1.92	1
	Change of (S)-Methadone	After Quetiapine, %	4-	107	-3	115	32	7	-18	23	59	٠.	-30	4-	4	33	23.37	43.44	0.12
	(S)-Methadone	Before Quetiapine, $ng \times d/mL \times mg$	1.51	1.31	1.41	1.86	0.80	2.37	2.33	0.84	1.53	3.76	4.48	1.22	2.72	0.99	1.94	1.10	I
riod of 30 Days	Change of (R)-Methadone	After Quetiapine, %	∞	28) m	42	9	20	-23	17	36	3	6-	œ	- 00	32	20.56	28.44	0.026
138 mg/d) for a Mean Period of 30	(R)-Methadone Before	Quetiapine, Aft ng × d/mL × mg Quetiap	1 38	27.1	1.53	2.55	1.07	1.93	1.83	1.45	1.57	3.84	3.64	1.18	1.90	1.13	1.91	0.87	1
138 mg,		Patient No.	-	۰, ۳	٦ ٩	۰ ،	, 42		- œ	, =	: :	3 5	4	17	10	30	Mean	SD	Д

methadone treatment at inclusion was 1332 days (SD, 1084 days; median, 1244 days; range, 162–3325 days). The mean dose of methadone was 121 mg/d (SD, 67 mg/d; median, 130 mg/d; range, 12–240 mg/d) at the first blood sampling (before quetiapine) and was 119 mg/d (SD, 68 mg/d; mean, 130 mg/d; range, 12–240 mg/d) at the second blood sampling. The mean quetiapine dose was 138 mg/d (SD, 87 mg/d; mean, 125 mg/d; range, 50–300 mg/d), which was administered for a mean duration of 30 days (SD, 8 days; mean, 30 days; range, 20–48 days). No quetiapine could be detected in the blood of patients before the introduction of quetiapine. At the second blood sampling, the mean quetiapine plasma level was 51 ng/mL (SD, 57 ng/mL; mean, 32 ng/mL; range, 3–183 ng/mL; Table 1).

All patients were found to be CYP3A5 PMs, with the *3/*3 genotype, a high prevalence of this allele confirming previous studies in whites.²¹ Two patients were found to be CYP2B6 *6/*6, a genotype found to be associated with decreased CYP2B6 activity and higher (S)-methadone plasma levels.² Three patients were found to be CYP2D6 PMs (*3/*4, 1 patient; *4/*4, 2 patients) and 11 to be EMs, either heterozygous (intermediate metabolizers or IMs, *1/*4 or *1/*3, 7 patients) or homozygous (*1/*1, 4 patients). No patient was found to be CYP2D6 ultrarapid metabolizer. Three patients were found to have the ABCB1 3435 TT genotype, which is generally associated with lower PGP activity²² due to reduced mRNA stability²³; 8 and 3 patients were found to have the ABCB1 3435 CT and CC genotypes, respectively. Quetiapine plasma levels-dose ratios were not significantly different between CYP2D6, CYP2B6, and ABCB1 genotypes (data not shown). Likewise, methadone plasma levels-dose ratios were not significantly different between ABCB1 and CYP2D6 genotypes (data not shown). On the other hand, (S)-methadone (P = 0.034), but not (R)-methadone (P = 0.10), plasma levels-dose ratios were significantly higher in the 2 patients with the CYP2B6 *6/*6 genotype as compared with the 9 patients with 0 or 1 *6 allele [mean (S)-methadone: 2.54 vs. 1.38 ng/mL × mg], which confirms a previous study showing a strong influence of this genotype on (S)-methadone plasma levels.2,5

A significant increase of methadone concentrationdose ratios was measured after introduction of quetiapine, in the whole group for (R)-methadone [increase for (R)-methadone: mean, +21%; SD, +28%; median, +13%; range, -23% to +85%; P = 0.026] but not for (S)-methadone (mean, +23%; SD, +43%; median, +6%; range, -30% to +115%; P = 0.120) or for (R,S)-methadone (mean, +21%; SD, +34%; median, +9%; range, -21% to +95%; P = 0.064). No significant correlations could be observed between the increases of the (R)-, (S)-, and (R,S)-methadone concentrationdose ratios measured after the introduction of quetiapine with quetiapine plasma levels (P = 0.71, 0.96, and 0.92,respectively). Although the changes of the methadone concentration-dose ratios observed after quetiapine administration were not significantly different between the CYP2B6, CYP2D6, and ABCB1 genotypes, possibly because of the low number of patients of each genotype, interestingly, the mean modifications of the (R)-methadone concentrationdose ratios were of 7%, 21%, and 30% in the CYP2D6 PMs, IMs, and EMs, respectively, whereas they were of 3%, 23%, and 33% in the subjects with the *ABCB1 3435 TT*, *CT*, and *CC* genotypes, respectively. Table 1 lists the mean methadone concentration-dose ratios measured before and after the introduction of quetiapine, with the *CYP2D6*, *CYP2B6*, and *ABCB1* genotypes.

DISCUSSION

The present result shows a weak (21%) but significant increase of the concentration-dose ratios of (R)-methadone, but not (S)-methadone, in patients in MMT after quetiapine administration. The absence of a significant effect on the (S)-enantiomer plasma levels could be due to the low number of patients included and to an insufficient power to detect a small change. Based on in vitro data, 12 it is not expected that this interaction is due to an inhibition by quetiapine of the CYP isoforms implicated in methadone metabolism. This is also supported by the lack of correlation between quetiapine plasma levels and increase of methadone concentration-dose ratios observed in this study. One can formulate the hypothesis that one or several quetiapine metabolite(s), which are produced in vivo¹¹ and which were not included in the in vitro interaction study performed by AstraZeneca (AstraZeneca, data in file), are responsible for this interaction. Alternative or additional mechanisms by which quetiapine and/or quetiapine metabolites could interact with methadone pharmacokinetics could be an inhibitory effect toward CYP2B6, which has not been tested in the above-mentioned study¹² (AstraZeneca, data in file) and/or an inhibitory effect toward the PGP transporter system.

With regard to CYP2B6, in vitro10 and in vivo2,5 studies showed a stereoselectivity of this isozyme toward the (S)-enantiomer, which is in apparent contradiction with the idea of an interaction with this isozyme to explain an increase of (R)-methadone concentration-dose ratios. With regard to the PGP transporter, a study using knockout mice suggested that it could display a stereoselectivity toward the (S)-enantiomer, 15 such a stereoselectivity being not confirmed in vivo.⁵ Interestingly, although no statistically significant differences were found between the different CYP and ABCBI genotypes, one can mention that the lowest increases of (R)-methadone concentrations were measured in the CYP2D6 PMs (7%) and in the patients with the ABCB1 3435 TT genotype (3%, not the same patients). Accordingly, higher increases were measured in the CYP2D6 IMs (21%) and in the patients with the ABCB1 3435 CT genotype (23%), whereas the highest increases were measured in the CYP2D6 EMs (30%) and in the patients with the ABCB1 3435 CC genotype (33%). This result is in agreement with a previous study showing an increase of (R)-methadone plasma levels in the CYP2D6 EMs but not in PMs after the administration of paroxetine, a strong CYP2D6 inhibitor,3 and is in agreement with the hypothesis that an inhibition of methadone metabolism and/or transport can be best observed in subjects with the highest baseline metabolic and/or transport activity. As CYP2D6 is not known to be expressed in the gut, a possible inhibition of CYP2D6 by quetiapine presumably occurs in the liver. On

the other hand, it is not known whether a possible inhibition of PGP by quetiapine occurs in the gut and/or in the liver. In addition, the present results do not allow to draw any conclusions on the possible interactions of quetiapine and/or of quetiapine's metabolites with CYP3A4, the other main CYP isoform with CYP2B6 implicated in methadone metabolism.

At least with a low mean daily dose of 138 mg of quetiapine administered during the present study, the mean 21% increase of the plasma concentration of (R)-methadone is weak and smaller than changes observed after the administration of other psychotropic drugs such as paroxetine,3 fluvoxamine, and fluoxetine8 and is unlikely to be of clinical importance. Thus, it is not expected that such a weak increase would result in clinically significant effects in relation to respiratory depression, due to the high tolerance of patients in maintenance treatment to the opioid effect of methadone. In the present study, no signs of overmedication or intoxication were noticed by the staff or reported by the patients despite the fact that an increase of (R)-methadone plasma levels-dose ratios up to 85% was measured in 1 patient. On the other hand, as the elimination half-life of quetiapine is short, that is, approximately 7 hours, 11 and as opioid withdrawal symptoms have been described after a sudden stop of fluvoxamine, such effects might theoretically also occur when quetiapine treatment is abruptly interrupted. In the present study, as quetiapine treatment continued after the second blood sampling, no such side effects were

Very recent studies show that methadone can prolong the OT interval and cause torsades de pointes, the use of high methadone doses being a risk factor. 24,25 Rare cases of QT-interval prolongation have also been shown with quetiapine. As the present study was conducted before the cases of torsades de pointes under methadone were published, no electrocardiography was performed, and we can therefore not draw any conclusions regarding this point. This must, however, clearly be examined in future studies, along with the use of higher quetiapine doses. From a practical point of view, considering the strong increase of methadone plasma levels in some patients after the introduction of various comedications, such as quetiapine, fluvoxamine, fluoxetine, or paroxetine, and considering the apparent unpredictability of this interaction (ie, which individuals would have an increase of methadone plasma levels and to what extent), therapeutic drug monitoring of the enantiomers of methadone, performed before and after the administrations of specific comedications known, likely or suspected to interact with methadone pharmacokinetics, can be a helpful tool in the clinical management of patients in MMT. The present study, as well as a previous study with paroxetine suggesting that the genetic status of the patients could strongly influence the interactions of comedications with methadone, clearly warrant future studies with larger numbers of genotyped patients, to confirm these results. In the future, this could hopefully allow to better predict the potential interactions occurring when administering comedications to patients in MMT.

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Adverse Events Reporting System (AERS) reports on seroquel/methadone combination overdoses

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FDA - Adverse Event Reporting System (AERS)

Outcome Death	Date:10/17/02ISR Numb	Outcome Life-Threatening	Date:10/17/02ISR Numb	Outcome Life-Threatening Hospitalization Initial or Prolonged	Date:10/17/02ISR Numb	Outcome Hospitalization — Initial or Prolonged	Date:10/17/02ISR Numbe	Outcome Other	Date:10/16/02ISR Numbo
PT Drug Ineffective Drug Interaction	Date:10/17/02ISR Number: 3997318-3Report Type:Expedited (15-DaCompany Report #2002UW13833	ET Confusional State hyperpyrexia Metabolic Acidosis Renal Failure Acute Respiratory Failure Rhabdomyolyais	Date:10/17/0ZISR Number: 3995665-ZReport Type:Expedited (15-DaCompany Report #2002SE05214	Alanine Aminotransferase Increased Aspartate Aminotransferase Increased Slood Alkaline Phosphatase Increased Gamma-Glutamyltransferase Increased Jaundice	Date:10/17/0215k Number: 3995664-OReport Type:Expedited (15-DaCompany Report #2002AP03042	PT Disseminated Intravascular Coagulation	Date:10/17/02I5R Number: 3995660-3Report Type:Expedited (15-DaCompany Report #2002SE05260	PT Bradycardia	Date:10/16/02ISR Number: 4012516-0Report Type:Periodic
Report Source Health Professional	dited (15-DaCompany Re	Report Source Foreign Health Professional Other	dited (15-DaCompany Re	Report Source Forcign Health Professional Other	dited (15-DaCompany Re	Report Source Foreign Health Professional Other	iited (15-DaCompany Re	Report Source Health Professional	
Product Seroquel Methadone	port #20020W13833	Product Seroquel	port #2002SE05214	Seroquel Seroquel Solanax Solanax Sepazon Seddel Depas Isomytal Hagnesium Oxide Amoban Yodel Paxil Paxil	port #2002AP03042	Product Seroquel	port #2002SE05260	Product Neurontin (Gabapentin) Quetiapine Paroxetine Hydrochloride	Company Report #001-0945-M0200505
Role Manufacturer PS SS		Role Manufacturer PS		SS		Role Manufacturer PS		Role Manufacturer PS SS	ŭ.
Route ORAL	Age:	ROULE	Age:40 YR	ORALL ORALL	Age:39 YR	Route	Age:60 YR	Route	Àge:
Dose 200 MG PO	Gender:Male	Dose 300 MG DAITY PO	Gender:Male	150 MG DAILY PO 250 MG DAILY PO		Dose	Gender:Male	Dose	Gender:Unknown
Duration	I/FU:I	Duration	I/EU:F	PHEATTON	I/FU:F	Duration	I/FU:I	Duracion	n I/FU:I

Date:11/06/02ISR Number: Outcome Required Antervention to Prevent Pormanent Impoirment/Damage	Outcome Required Intervention to Frevent Permanent Impairment/Damage	Date:11/08/02ISR Num	Outcome Death	Date:11/07/02I5R Numi	Outcome Death	Date: 11/07/02ISR Numb	Outcome Hospitalization - Hospitalization - Initial or Prolonged	Date:11/07/02ISR Numb	Outcome Death	Date:11/07/02ISR Numb
ber: 4009529-lReport Type: PT Neutropenia	PT Herpes Zoster Leukopenia Rash Macular	Date:11/08/02ISR Number: 4009519-9Report Type:Expedited (15-DaCompany Report #20025E05579	PT Sudden Death	Date:11/07/02I5R Number: 4009290-OReport Type:Expedited (15-DaCompany Report #20025E05653	PT Death	Date:11/07/02ISR Number: 4009253-5Report Type:Expedited (15-DaCompany Report #2002UW14645	P Angina Pectoris Nyocardial Infarction	Date:11/07/02ISR Number: 4009159-XReport Type:Expedited (15-DaCompany Report #2002UW14867	PT Completed Suicide Intentional Overdose	Dato:11/07/02ISR Number: 4009076-7Report Type:Expedited (15-DaCompany Report #2002AP03574
4009529-lReport Type:Expedited (15-DaCompany Report #20025E05604 Pr Report Source Product Foreign Seroquel Health Professional Other	Report Source Foreign Health Professional Other	sxpedited (15-DaCompany Re	Report Source Foreign Health Professional Other	xpedited (15-DaCompany Re	Report Source Consumer	xpedited (15-DaCompany Re	Report Source Health Professional	xpedited (15-DaCompany Rep	Report Source Literature Health Professional	xpedited (15-DaCompany Rep
port #20025E05604 Product Seroquel	Product Seroquel Seroquel Lexotanil Akineton Stelazine Granulokine Lithium	port #20025E05579	Product Seroquel Methadone Benzodiazepine	port #20025E05653	Product Seroquel	port #2002UW14645	Product Seroquel Altace Lopressor Indur Plavix Zocor "Dieckmann"	port #2002UW14867	Product Propranolol Quetiapine Alprazolam	ort #2002AP03574
Role Manufacturer PS	Role Manufacturer PS SS C C C C		Role Manufacturer PS C C		Role Manufacturer PS		Role Manufacturer PS C C C C		Role Manufacturer PS SS SS	
Age: Route ORAL	Route GRAL ORAL	Age:40 YR	Route	Age:	Route	Age:35 YR	Route	Age:33 YR	Route	Age:32 YR
Gender:Female Dose 2002 MG QD PO	BOOMS QD PO 400 MG QD PO	Gender:Femalo	Dose	Gunder:Male	Dose	Gender:Male	Dase	Gender:Male	Dase	Gender:
e I/FU:I. Duration PO	O DUXACION	e I/FU:I	Duration	I/FU:I	Duration	I/FU:I	Duration	1/FU:1	Duration	1/FU:1

		Outcome	Date:12/18/02ISR Number:		Initial or Prolonged			Date:12/17/02ISR Number:											onged	Hospitalization - E		Date:12/17/02ISR Number:	1			Death B		Date:12/16/02ISR Number:
		PT Movement Disorder	Date:12/18/02ISR Number: 4025/25-IReport Type: officer		Intravascular Coagulation Drug Toxicity	PT Coma Disseminated		Date:12/17/02ISR Number: 4028692-XReport Type:Expedited (15-DaCompany Report #20028805260						Schizophrenia	Insomnia Respiratory Distress	Hallucination Hypoventilation	Diabetes Mellitus	Condition Aggravated Decreased Appetite	Phosphokinase Increased Blood Fressure Increased	Blood Creatine	T9	4028525-1Report Type:Expedited (15-DaCompany Report #APCD552002000429	Road Trailic Accident Toxicologic Test Abnormal	Pulmonary Ocdema	Injury	Bronchopneumonia		Date:12/16/02ISR Number: 4026990-7Report Type:Expedited (15-DaCompany Report #2000UWD0285
		Report Source			Professional Other	Report Source Foreign Health	7	ted (15-DaCcmpany Rep											Professional	Foreign	Report Source	ted (15-DaCompany Repo			Professionar	Health	Report Source	ed (15-DaCompany Repo
Affacer Afface Altace Valproic Acid Prevacid Kionopin Glucophag Motrin	Astra Zeneca Geodon 80mg Caps	Product Seroquel 300mg Tabs		Company Remort #CTU 183007	Stilnoct Trazolan	Seroquel Haldol "Janssen"	Product	ort #2002SE05260	(Biperiden Hydrochloride)	Hydrochloride	(Zopiclone)	Zopiclone	(Estazolam)	(Hydroxyzine)	Hydroxyzine Pamoate	Fumarate)	Quetiapine Fumarate	(Haloperidol)	(Arabertaone)	Risperdal (Tablet)	Product	ort #APCDSS2002000429	(a a c c c c c c c c c c c c c c c c c	Nortriptyline	Amitriptyline	Seroquel "Zeneca"	Product)rt #2000UW00285
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E 1 7 5 6 1	Astra Geneca	Manuraccurer					Manufacturer														Manufacturer					Zeneca	Manufacturer	
CENT	OBAL	OBAL	7	Age:39 YR			Route	Age:58 YR								ORAL		ORAL		ORA1	Route	Age:37 YR					Route	Age:21 YR
	ADMG PO BID	SHO OR SMOOS	Dose	Gender:Female			Dose	Gender:Male								MG, DAILY,		MG, DAILY, ORAL	ORAL	MG, DAILY,	Dose	Gender:Male					Dose	Gender:Male
	- 1		Duration	e I/FU:I			Duration	I/FU:F													Duration	1/FU:F					Duration	1/EU: E

Outcome Death	Date: 12/23/02ISR N	Outcome Other	Date:12/23/02ISR Nu	Outcome Hospitalization - Initial or Prolonged	Date:12/23/02ISR Nu		Outcome Death	Date:12/23/02ISR Nu	Outcome Other	Date:12/23/02TSR Nui
PT Drug Interaction Lethargy Malaise	Date:12/23/02ISR Number: 4033027-2Report Type:Expedited (15-DaCompany Report #2002AP043B0	PT Red Blood Cell Count Decreased	Date:12/23/02ISR Number: 4033025-9Report Type:Expedited (15-DaCompany Report #2002UW17079	PT Liver Function Test Abnormal Lymphocyte Count Decreased Hononucleosis Syndrome Reutrophil Count Becreased White Blood Ceil Count Decreased	Date:12/23/02ISR Number: 4032431-6Report Type:Expedited (15-DaCompany Report #2002UW17056	overzosa	PT Drug Toxicity	Date:12/23/02ISR Number: 4032361-XReport Type:Expedited (15-DaCompany Report #B0287819A	PT Sommolence	Date:12/23/02TSR Number: 4029135-2Report Type:Direct
Report Source Foreign Health Professional Other	pedited (15-DaCompany R	Report Source Foreign Health Professional Other	pedited (15-DaCompany Ro	Report Source Enceign Health Professional	edited (15-DaCompany Re		Report Source Foreign	edited (15-DaCompany Re	Report Source	
Product Seroquel Methadone	eport #2002AP043B0	Product Seroquel Neurontin Ativan Dicetel Imovane Prevacid Clonazapam Vitamin B12 Synthroid	eport #2002UW17079	Product Seroquel Wellbutin	sport #2002UW17056	Quetiapine Fumarate (Quetiapine Fumarate) Fumarate) Dextropropoxyphene (Dextropropoxyphene)	Product Paracetamol (Acetaminophen)	port #80287819A	Product Quetiapine 50 Mg Bid Po	Company Report ⊭CTU 183279
Role PS SS		Role Role		Role PS C		•	Role		d PS	
Manufacturer		Manufacturez		Manuƙacturer			Manufacturer		Manufacturer	
Route	Age:41 YR	Route	Age:49 YR	Route	Age:14 YR	ORAL	Route ORAL	Age:38 YR	Route	Äge:
Dose	Gender:Male	Do se	Gender:Female	Dose Duration 50 MG BID PO	Gender:Male	ORAL	ORAL	Gender:Male	Dose	Gender:
Duration	I/FU:I	Duration	e 1/FU:I	Duration	I/FU:I		puracion	I/FU:I	Duration	1/60:1

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FDA - Adverse Event Reporting System (AERS)

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Outcome Hospialization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Date:12/27/02ISR Numbe	Outcome Death	Date:12/27/02ISR Numbe	Outcome Hospitalization - Initial or Prolonged	Date:12/27/02ISR Numbe	Outcome Required Intervention to Frevent Permanent Impairment/Damage	Date:12/27/02ISR Numbe	
PT Drug Withdrawal Syndrome Neonatal Hypervigiance Hypervonia Meonatal Induced Labour Insomnia Maternal Drugs Affecting Foetus Neonatal Disorder	Datc:12/27/02ISR Number: 4034993-lReport Type:Expedited (15-DaCompany Report #20026B02891	PT Anger Drug Abuser Parkinson's Disease	Date:12/27/02ISR Number: 4034747-6Report Type:Expedited (15-DaCompany Report #2002071920	PT Leukopenia Neutropenia	Date:12/27/02ISR Number: 4034466-6Report Type:Expedited (15-DaCompany Report #2002SE06332	PT Menstruation Irregular Thrombocytopenia	Date:12/27/02ISR Number: 4034463-OReport Type:Expedited (15-DaCompany Report #2002SE06067	White Blood Call Count Decreased
Report Source Foreign Health Professional Other	edited (15-DaCompany Re	Report Source Foreign Health Professional	edited (15-DaCompany Rep	Report Source Foreign Health Professional Other	edited (15-DaCompany Rep	Report Source Foreign Health Professional Other	dited (15-DaCompany Rep	Report Source Foreign Health Professional Other
Product Quettapine Paroxetine Pethidine	port #2002GB02891	Product Zoloft (Settraline) Quetiapine Methadone Chlorpromazine Cloriapine Delorazepam Flurazepam	port #2002071920	Product Sercquel Serchase Femesta Thyroxin Burana	bort #2002SE06332	Product Seroquel Xanax	ort #2002SE06067	Product Seroquel Wellbutrin
Role Manufacturer PS SS C		PS Manufacturer SS SS C C C C C C C C C C C C C C C C		Role Manufacturer PS C C C C		Role Manufacturer PS C		Role Manufacturer PS C
Route TOPICAL TOPICAL	Age:	Route ORAL ORAL ORAL	Age:45 YR	Route ORAL	Age:62 YR	Route ORAL	Age:22 YR	ROUTE ORAL
Dose Duration 400 MG BID TPL DEL 20 MG QD TPL	Gender:Female I/FU:I	Dose Duration 20 MG (PAILY), ORAL ORAL TO MG (PAILY), ORAL	Gender:Male I/FU:I	Dose 100 MG QID PO	Gender:Female I/FU:I	Dose Duration 600 MG QD PO	Gender:Female I/FU:F	Dose 50 MG BID FO

Freedom Of Information (FOI) Report

Initial or Prolonged

Outcome Death	Date:07/29/03ISR Num	Outcome Disability Required Intervention to Prevent Permanent Impairment/Damage	Date:07/29/03ISR Numb	Outcome Other	Date:07/29/03ISR Numb	Outcome Life-Threatening	Date:07/29/03ISR Numb	
PT Drug Interaction Sedation	Date:07/29/03ISR Number: 4159627-7Report Type:Expedited (15-DaCompany Report #2003UW09220	PT Hypersensitivity	Date:07/29/03ISR Number: 4159249-BReport Type:Expedited (15-DaCompany Report #2003GB01547	PT Electrocardiogiam Abnormal Leukopenia	Date:07/29/03ISR Number: 4159248-6Report Type:Expedited (15-DaCompany Report #2003GB02021	PT Mental Retardation Road Traffic Accident	Date:07/29/03ISR Number: 4157512-BReport Type:Direct	Agression Agranulocytosis Anglan Fectoris C-Reactive Protein Increased Cough Depression Discrientation Discrientation Discriess Dysphoea Lung Infection Nettropenia Pyrexia Restlessness Rhomehi Sputum Discoloured Vascular Dementia Wheezing
Report Source Health Professional	ited (15-DaCompany Rep	Report Source Foreign Health Professional Other	ited (15-DaCompany Rep	Report Source Foreign Health Professional Other	ited (15-DaCompany Rep	Report Source		Report Source Foreign Health Professional Other
Product Seroquel Methadone	part #2003UW09220	Product Seroquel Sertaline Depakote Chlorpromazinc	ort #2003GB01547	Product Seroquel Seroxat	ort #2003GB02021	Product Seroquel Lithium	Company Report #CTU 198893	Product Aldactone(Spironolac tone) Tablet Seroquel(Quetiapine) Torem(Torasemide) Marcoumar (Phenprocoumon) Beloc Zok (Metoprolol Succinate)
Role PS SS		Role PS C C		Role PS C		Role PS SS		C C SSS PROLE
Manufacturer		Manufacturer		Manufacturer Ciba-Geigy		Manufacturer		Manufacturer
Route	Age:30 YR	Route ORAL	Age:29 YR	Route	Age:	Route	Age:34 YR	Route ORAL ORAL ORAL
Dose	Gender:Female	Dose 50 MG ONCE PO	Gender:Female	Dase	Gender:Female	Dose	Gender:	Dose 50 MG, DAILY, ORAL 10 MG DAILY, ORAL
Duration	e I/FU:I	Duration PO	I/FU:F	Duration	1/FU:I	Duration	I/FU:I	Durz

Tuttal of krotori	Death Hospitalization -	Outcome	Date:08/29/03ISR Numbe	Outcome	Date:08/28/03ISR Numbe		Outcome Hospitalization - Initial or Prolonged Other	Date:08/28/03ISR Numbe	Outcome	Date:08/27/03ISR Number	Death	Date:08/27/03ISR Number
Vellet cerrore	Neuroleptic Malignant Syndrome	PT	Date:08/29/0315R Number: 4175730-XReport Type:Expedited (15-DaCompany Report #GB-BRISTOL-MYERS SQUIBB COMPANY-12363263	PT Agitation Drug Interaction Hallucination	Date:08/28/0315R Number: 4175192-2Report Type:Periodic		PT Blood Glucose Increased Diabetes Mellitus	Date:08/28/03ISR Number: 4175080-lReport Type:Periodic	PT Chest Pain Drug Interaction Hypotension Supraventricular Tachycardia	Date:08/27/03ISR Number: 4181188-7Report Type:Expedited (15-DaCompany Report #M0929-03	Drug Toxicity Hepatic Cirrhosis Pulmonary Congestion Pulmonary Oedema	Date:08/27/03ISR Number: 4180639-XReport Type:Expedited (15-DaCompany Report #2003UW10563 Outcome PT Report Source Product
		Report Source	edited {15~DaCompany Rep	Report Source			Report Source		Report Source	dited (15-DaCompany Repo	Health Professional	dited (15-DaCompany Repo
Pabs Quetiapine Fumarate	Sinemet Cr Tabs Carbidopa + Levodopa	Product	ort #GB-BRISTOL-MYERS S	Product Abilify Tabs Seroquel	Company Report #US-BRISTOL-MYERS SQUIBB COMPANY-12291316	Seroquel Valproic Acid Haldol	Product Abilify Tabs 10 Mg	Company Report #US-BRISTOL-MYERS SQUIBB COMPANY-12246666	product Mittazpine Seroquel Atropine Sulfate Oxazepam	ort HM0929-03	Seroquel Methadone Zoloft	Product
ស		Role	Gainð	I bs boye	QUIBB C	ccs	Role PS	DOIBB C	Role PS SS SS		0.0 %	Role
Bristol-Myers Squibb Company	Company	Manufacturer	COMPANY-12363263	Manutacturer Otsuka Pharmaceutical Company, Ltd.	COMPANY-12291316		Manufacturer Otsuka Pharmaceutical Company, Itd.	OMPANY-12246666	Manufacturer			Manufacturer
ORAL	ORAL	Route	Age:59 YR	Kouce	Age:		Route	Age:41 YR	ROUTE ORAL ORAL PARENTERAL	Age:45 YR	ONCE	Age:47 YR Route
narrative stated "20, once a day" and daily dose block on	"at bedtime"	Dose	Gender:Male	i de	Gender:		Dose	Gender:Male	Dose 60 MG ORAL 300 MG ORAL 0.5 MG PARENTERAL	Gender:Female	PO	Gender:Female Dose Roo MG DATLY
מ	-	Duration	I/FU:F		I/FU:I		Duration 4 DAY	I/EU:F	nuracion 1 DAY	1/60:1		I/FU:I Duration

Freedom Of Information (FOI) Report

Date:09/26/03ISR Numb	Outcome Other	Date:09/25/03ISR Numbe	Outcome Death	Date:09/25/03ISR Numbe		Hospitalization - Initial or Prolonged	Outcome	Date:09/25/03ISR Numbe	
Date:09/26/03ISR Number: 4197110-3Report Type:Direct	PT Thrombocytopenia	hate:09/25/03ISR Number: 4200922-OReport Type:Expedited (15-DaCompany Report #7003GB023BB	PT Drug Toxicity Hepatic Cirrhosis Medication Error Pulmonary Congestion Pulmonary Oedema	Date:09/25/03ISR Number: 4200713-OReport Type:Expedited (15-DaCompany Report #2003UW10563	Stevens-Johnson Syndrome	Face Oedema Insomnia Oedema	PT	Date:09/25/03ISR Number: 4200659-8Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20030904254	Hypertonia Neonatal Maternal Drugs Affecting Foctus Foctus Hasal Flaring Neonatal Disorder Neonatal Respiratory Distress Syndrome Oxygen Saturation Decreased Respiratory Disorder Neonatal Respiratory Rate Increased Meight Decreased Weight Gain Poor
	Report Source Foreign Health Professional Other	edited (15-DaCompany Re	Report Source Health Professional	dited (15-DaCompany Re		Foreign Health Professional	Report Source	dited (15-DaCompany Re	Report Source Foreign Health Professional Other
Company Report #CTU 202721	Product Seroquel Digoxin Warferin Atenolol	eport #2003GB023B8	Product Seroquel Methadone Zoloft	port #2003UW10563	Quetiapine (Quetiapine) Unknown	(Risperidone) Unspecified	Product	port #JP-JNJFOC-200309	Product Seroquel Lorazepam
	Role PS C		Role PS C		wn ss	Sa	Role	04254	Role PS SS
	e Manufacturer		Manufacturer				Manufacturer		Manufacturer
Age:27 YR	Route	Age:	Route	Age:47 YR	ORAL	ORAL	Route	Age:67 YR	ROUTE TRANSPLACENTAL TRANSPLACENTAL
Gender:Male	Dose PT ON SEROQUEL FOR 2-3 WEEKS	Gender:Male	Dase 400 MG DAILY PO	Gender:Female	2 MG IN 1 DAY ORAL	2 MG IN 1 DAY ORAL	Dosc	Gender:Male	Dose 150 MG QTD TPL, 2 MG TID TPL
1/FU:1	Duration	I/FU:I	Duration	I/FU:F			Duration	1/60:1	Duration

Outcome
Life-Threatening
Required
Intervention to
Provent Permanent

Outcome Required Intervention to Prevent Bermanent Impairment/Damage	Date:09/26/03ISR Numbe	Outcome Life-Threatening Hospitalization - Initial or Prolonged	Date:09/26/0315R Number		Intervention to Prevent Permanent Impairment/Damage	Outcome Required	Date:09/26/03I5R Number	Outcome Hospitalization - Initial or Prolonged	Date:09/26/03ISR Number	Outcome Hospitalization - Initial or Prolonged	Date:09/26/03ISR Number
en cataract	Date:09/26/0315R Number: 4210385-7Report Type:Periodic	PT Grand Mal Convulsion	Date:09/26/03ISR Number: 4210384-5Report Type:Periodic	Increased Body Temperature Increased Eye Pain Ocular Hyperacmia Vision Blurred Weight Increased	Blood Cholesterol Increased Blood Triglycerides	PT Angle Closure Glaucoma	Date:09/26/03T5R Number: 4210383-3Report Type:Periodic	PT Urinary Retention	Date:09/26/03ISR Number: 4210382-lReport Type:Periodic	PT Electrocardiogram Qt Prolonged	Date:09/26/D3ISR Number: 4210381-KReport Type:Periodic
Report Source Health Professional		Report Source Health Professional				Report Source Consumer		Report Source Health Professional		Report Source Health Professional	
Product Seroquel Paxil Huspar Trilafon Amantadine	Company Report #2003UW05072	Seroquel Seroquel Genoden Risperdal Clonidine Depakote Zyprewa Prolixin Klonopin	Company Report #20030W04581	Celesa Risperdal Lexapro Desyrel Trileptal	Seroquel	Product Seroquel	Company Report #2003UW04615	Product Seroquel	Company Report #2003UW04380	Product Seroquel Methadone	Company Report #2003UWD4343
Role Manufacturer PS C C C		Role Manufacturer PS SS G C C C C C C C C C C C C C C C C C) 15 15	Role Manufacturer PS		Role Manufacturer PS		C Se Manuraconrer	
Route ORAL	Age:50 YR	Route ORAL ORAL	Age: 25 YR		ORAL	Route ORAL	Age:32 YR	Route ORAL	Age:50 YR	ORAL	Age:39 YR
Dose 600 MG DAILY PO	Gender:Male	1000 HG PO 1000 HG PO			200 MG DAILY PO	Dose 100 MG DAILY	Gender:Female	Dose DAILY 300 MG DAILY PO	Gender:Male	100 MG DAILY	Gender:Female
Duration	I/EU:I	מאפרסט	1/FU:1			Duration	1/FU:I	Duration	1/FU:I		I/FU:I

24-Aug-2010 10:39 AM		Outcome	Date:11/03/03ISR Number: 4226882-4Report Type:Expedited (15-DaCompany Report #2003-DE-051256D	Outcome PT Hospitalization - Abi Initial or Prolonged Dro Epi Pla	Date:11/03/03ISR Number: 4226854-XReport Type:Expedited (15-DaCompany Report #2003UW13857	Outcome PT MyCheshitalization - Meu Neu Initial or Prolonged Syr	Date:11/03/03IsR Number: 4226629-IReport Type:Expedited (15-DaCompany Report #20036802744	Outcome PT Required Intervention to Free Prevent Permanent Hyp Impairment/Damage Foe Neo	Date:1170370315R Number: 4226124-XReport Type:Expedited (15-DaCompany Report #2003UW13923	Outcome Prace Required Anx Intervention to Ball Prevent Extmanent III Impairment/Damage Med Hus Mus Par	Date:11/03/D3TSR Number: 4226098-1Report Type:Expedited (15-DaCompany Report #20030W13607	Outcome PT Death Slev	Date:111/03/03TSR Number: 4226096-BReport Type:Expedited (15-DaCompany Report #2003UW13821
	Completed Suicide Multiple Drug Overdose	•	226882-4Report Type:Exped	PT Annormal Behaviour Drug Effect Decreased Epistaxis Platelet Count Decreased	226854-XReport Type:Expedi	PT Vyocardial Infarction Neuroleptic Mallgnant Syndrome Pheumonia Aspiration Pulmonary Embolism	.26629-lReport Type:Expedi	PT Drug Withdrawal Syndrome Reeling Jittery Hypertonia Neonatal Waternal Drugs Affecting Foetus Neonatal Disorder	26124-XReport Type:Expedi	er Balance Disorder Ill-befined Disorder Hedication Error Memory Impairment Muscle Spasms Muscle Twitching	26098-1Report Type:Expedi	PT Sleep Apnoea Syndrome	26096-BReport Type:Expedii
	Literature	Report Source	ited (15-DaCompany Rep	Report Source Foreign Health Professional Other	ted (15-DaCompany Repo	Report Source Foreagn Health Professional Other	ted (15-DaCompany Repo	Report Source Health Professional	ted (15-DaCompany Ropo	Report Source Consumer	ted (15-DaCompany Repo	Report Source Health Professional	ed (15-DaCompany Repo
	(Methadone)	Product	ort #2003-DE-05125GD	Product Seroquel Calcium Tylenol Isopto Olanzapine	ort #2003UW13857	Product Seroquel Carbama zepine Losec Akineton	ort #2003GB02744	Product Seroquel	rt #2003UW13923	Product Seroquel Serone Serione Paxil	rt #20030W13607	Product Seroquel	rt #20030W13821
	PS	Role		PS C C C		PS C C C		PS PS		C SS BS WOTE		Role PS	
		Manufacturer		Manufacturer		Manufacturer		Kanufacturer		Manuxaccuxer	•	Manufacturer	
	ORAL	Route	Age:39 YR	Route	Age:77 YR	Route ORAL	Age:55 YR	ROULTE	Age:	ORAL	Age:58 YR	Route ORAL	Åge:
	PO	Dose	Gender:	Dose	Gender:Female	Dose 300 MG BID PO	Gender:Male	Do s	Gender:	FO MG ONCE		Dose Duration 1200 MG QD PO	Gender:Female
•	Page: 823	Duration	1/EU:1	puration	I/EU:I	Duration PO	I/FU:F	Duration	I/FU:I		I/FU:I	Duration	I/EU:I

Freedom Of Information (FOI) Report

	Outcome Death	Date:12/29/03ISR Number:	Outcome I Required Intervention to Prevent Permanent Impairment/Damage	Date:12/29/03ISR Number:				Outcome PT Hospitalization - Ac Initial or Prolonged Ca	Date:12/29/03ISR Number: 4	٠	ge d	Outcome Hospitalization - Ar
	PT Drug Toxicity Multiple Drug Overdose	Date:12/29/03ISR Number: 4261718-7Report Type:Expedited (15-DaCompany Report #2003UW16557	PT Leukopenia Neutropenia	Date:12/29/03I5R Number: 4261670-4Report Type:Direct			Electroencephalogiam Abnormal Hallucinations, Mixed	PT Acute Psychosis Catatonia	Date:12/29/03ISR Number: 4261489-4Report Type:Expedited (15-DaCompany Report #2003120450		Blood Sodium Decreased Circulatory Collapse Eye Disorder Hypokalaemia	Outcome Report Source Product Hospitalization - Arrhythmia Foreign Seroquel "Zen
	Report Source Health Professional	lted (15-DaCompany Rep	Report Source					Report Source Health Professional	ed (15-DaCompany Repo		Study Health Professional Other	Report Source Foreign
	Product Seroquel	ort #2003UW16557	Product Quietapine Effexor Xr	Company Report MCTU 208905	(Estradiol, Norethisterone) Levothyroxine Sodium (Levothyroxine Sodium) Clonazepam (Clonazepam)	Zolott (Settraline) Northiptyline (Northiptyline) Carbamazepine) (Carbamazepine) (Garbamazepine) Morphine Sulfate (Morphine Sulfate)	Quetiapine Fumarate (Quetiapine Fumarate)	Neurontin (Gabapentin)	rt #2003120450	Euphylong Karrezide L-Thyroxin Kelperon Ct-Arzacimittel Noveril Mittazepin Temazepam	Seroquel Zeneca	Product Seroquel "Zeneca"
	Role PS SS		Role PS		0 0 0		u u	Sd		aaaa aaa	2 2 2	Role PS
	Manufacturer		Manufacturer						Man fart iter			Manufacturer
	Route ORAL ORAL	Age:33 YR	Route ORAL	Age:18 YR			ORAL	ORAL	Age:49 YR Route		ORAL	Route ORAL
rage. o.e	DOSE DUFALLUM 1000 MG QD PO 5 MON 1000 MG QD PO	Gender:Female	Dose Duration P.O. 350 MG/DAY	::Маlе			ORAL	MG (TID),	Gender:Female I/FU:I		PO MG DAILY	Dose Duration 300 MG DAILY PO

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

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Prevent Permanent Impairment/Damage	Required Intervention to	Outcome	Date:04/01/04I5R Numb	Outcome Required Intervention to Provent Permahent Impairment/Damage	Date:04/01/04ISR Numbe					TUTETAL OF STORMINGS	Outcome Hospitalization -		na+e-04/01/04ISR Numbe		Outcome Life-Threatening	Date:04/01/04ISR Numbe:		
Spicidal Ideation	Medication Error Panic Attack	PT Depression	Date:04/01/04ISR Number: 4333240-OReport Type:Expedited (15-DaCompany Report #2004UM05900	PT Loss Of Consciousness Medication Error Overdose	Date:04/01/04ISR Number: 4333234-SReport Type:Expedited (15-DaCompany Report #2004UWD5863	Proteinuria Qrs Axis Abnormal Ventricular Extrasystoles	Mobility Decreased Myoglobin Blood Increased	Fall Hypertension	Cerebral Atrophy Electrocardiogram Q Waves	Phosphokinase Mb	Aortic Valve Incompetence	7	ns+s-nd/01/04ISR Number: 4333217-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040202825	Phosphokihase incressed Fracture Pyrekia Thrombocytopenia	PT Blood Creatine	Date:04/01/04ISR Number: 4332497-XReport Type:Expedited (15-DaCompany Report #2003AP03972		
		Report Source Consumer	dited (15-DaCompany	Report Source Health Professional	dited (15-DaCompany F					Professional	Study Health	Report Source	dited (15-DaCompany R	Professional Other	Report Source Foreign	lited (15-DaCompany Re		Collect
Neurontin Skelaxin	Serzone	Product Seroquel	Report #2004UW05900	Product Seroquel	Report #2004UW05863	(Lorazepam)	Perphenazine) Lorazepam	(Ziprasidone)	(Quetiapine)	Olanzapine)	Risperidone (Risperidone)	Product	eport #US-JNJFOC-200402	Cravit Telesmin Risperdal Gramalil	Product Seroquel	port #2003AP03972	Diltizem Surgam Madopar	Product
0.0	SS	Role Manufacturer PS		Role Manufacturer PS		n	SS	SS	SS	SS	Sa	Role Manufacturer	202825	A A A A	Role Manufacturer PS		<i>ი</i> ი ი	Role Manufacturer PS
	ORAL	ORAL	Age:50 YR	Route	Age:		ORAL	ORAL	ORAL	ORAL	ORAL	Route	Age:80 YR		Route ORAL	Age:77 YR		Route ORAL
	500 MG DAILY	500 MG DAILY	ດ	Doge	Gender:Male		ORAL	ORAL	ORAL	ORAL	ORAL	Dose	Gender:Male		Dose DUTATION 100 MG DAILY PO	Gender:Male		Dose 50 MG DAILY FO
ı	LY 7 YR		I/FU:I		I/FU:I							Duration	I/FU:F		Dutation	1/FU:F		Duration

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Freedom Of Information (FOI) Report

Nicotine (Nicotine) SS Lidocaine (Lidocaine) SS

Page: 1000							
CE	13800 MG ONCE	Route ORAL	Role Manufacturer PS	Product Seroquel	Report Source Health Professional	PT Completed Suicide	Outcome Death
pecifil/FU:F	Gender:Not Specifil/FU:F	Age: 47 YR		Report #2004UW09918	pedited (15-DaCompany	Date:06/22/04ISR Number: 4385398-SReport Type:Expedited (15-DaCompany Report #2004UW09918	Date:06/22/04ISR Nu
			PS	Seroquel	Health Professional	Anaemia Anaemia	Other
Duration	Dose	Route	Role Manufacturer	Product	Report Source		
1/FU:1	Gender:Male	Age:76 YR		Report #2004UW12429	pedited (15-DaCompany	hate-06/22/04TSR Number: 4385384-5Report Type:Expedited (15-DaCompany Report #2004UW12429	nate:06/22/04ISR Nu
			C	famictal			Initial or Frotonded
- Catal	200 MG PO; 100 MG PO	Route ORAL	Role Manufacturer PS	Product Seroquel	Report Source Health Professional	er Bradycardia	Outcome Hospitalization -
I/FU:I	Gender:Male	Age:		teport #2004UW12369	sedited (15-DaCompany F	Date:06/22/04ISR Number: 4385383-3Report Type:Expedited (15-DaCompany Report #20049W12369	Date: 06/22/04ISR Nu
_	500 MG QD FO	ORAL		Seroquel Zyprexa	Health Professional	White Blood Cell Count Decreased	Outcome Other
Duration	Dose	Route	Role Manufacturer	Product	Denort Source		Date: 00/22/01125 No.
1/FU:I	Gender:Male	Age:24 YR		eport #20040W12540	edited (15-DaCompany F	n	יייי פיייייייייייייייייייייייייייייייי
						4	rrevent rermanent Impairment/Damage
			SS	Seroquel Lichium	Health Professional	Blood Creatine Phosphokinase Increased Programmer This This This This This This This This	Required Intervention to
Duration	Dose	Route	Role Manufacturer	Product	Report Source	Tq	Distrome
I/FU:I	Gender:	Åge:		eport #2004UW12511	edited (15-DaCompany R	Date:06/22/0415R Number: 4395380-BReport Type:Expedited (15-DaCompany Report #2004UW12511	Date:06/22/0415R Nur
			co Co	(Quetiapine)			
				Quetiapine			
			w w	Alprazlam (Alprazolam)			
			មនុ	(Methadone)			
			5.5	Hydrochloride)	Other	Drug Dependence Multiple Drug Overdose	Other
				Oxycontin Tablets	Report Source	PT Accidental Overdose	Outcome Death
Duration	Dose	Route	Hole Manufacturer			•	
I'EN:I	Gender:Female	Age: 40 YR		Company Report #USA-2003-0012008		h	5-+0-06/31/04TSH Num

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FDA - Adverse Event Reporting System (AERS)

Outcome Hospitalization - Initial or Prolonged	Date:11/17/04ISR Numbe						Hospitalization - Initial or Prolonged	Outcome	Date:11/17/04ISR Numbex:	Outcome Hospitalization - Initial or Prolonged	Date:11/17/04ISR Numbes
ET Confusional State	Date:11/17/04ISR Number: 4505145-3Report Type:Direct						Hypotension Mental Status Changes	PT	r: 4504471-lReport Type:Direct	PT Abnormal Behaviour Communication Disorder Neuroleptic Malignant Syndrome	Date:11/17/04ISR Number: 4504434-6Report Type:Direct
Report Source	Company Re							Report Source	Company Rep	Report Source	Company Rep
Product Ouetinpine Methadone Lorazepam Ass Plavix Lopid Lisinopril Hetoprolol Naproxen	Company Report #CTU 232218	Diazepam Inj Clopidogrel Bisulfate Tab Aspirin Tab	Cap, Sa Thiamine Hcl Tab Folic Acid Tab Metoprolol Tartrate Tab	Tab Lisinopril Tab Omeprazole (Prilosec For Inpatient Use)	(Dosyrel) Tab Sertraline Hcl (Zoloft) Tab Gabapentin Cap Simvastatin (Zocor)	Nicotine Transdermal Nicotine Transdermal Patch Insulin, Human Reg, Novolin-R Oxycodone/Acetaminop	Tablet Prednisone Tab	Product	Company Report #CTU 232322	Product Secoquel 100 Hg Risperdal 2 Hg Zoloft Valproic Acid	Company Report #CTU 232346
CCCCCCCCCCCCCCCCCCCCCCCCCCCCCCCCCCCCCC		00 0	ი იიი	αn	00 0		S.	Role		Role PS SS	
Manufacturer								Manufacturer		Manufacturer	
Route	Age:58 YR						ORAL	Route	Age:57 YR	Route ORAL ORAL	Age:
Dose 400 ML OHS 8 ML O B H O S ML BID 1H Q HS	Gender:Male						100MG HS, BY MOUTH	Dose	Gender:Male	Dose I 100 MG PO BID 2 MG PO QHS	Gender:Male
Duration	I/FU:I							Duration	1/FU:I	Duration 6 MON 6 MON	I/FU:I

Freedom Of Information (FOI) Report

Olanzapine (Olanzapine)

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Outcome Other	Date:03/15/05ISR Numi	Outcome Hospitalization - Initial or Prolonged	Date:03/15/05ISR Numb		Outcome Hospitalization -	Date:03/15/05ISR Number:	Outcome Other	Date:03/14/05ISR Numbe	Outcome	Date:03/14/05ISR Numbe
PT Ansemia kaline Blood Alkaline Blood John Decreased Haemoglobin Decreased Malaise Pancytopenia Platelet Count Decreased	Date:03/15/05ISR Number: 4608612-7Report Type:Expedited (15-DaCompany Report #PHBS2004JP17256	PT Drug Interaction	Date:03/15/05ISR Number: 4608486-4Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0549464A	;	PT Drug Interaction Ill-Defined Disorder	er: 4608485-2Report Type:Expedited (15-DaCompany Roport #US-GLAXOSMITHKLINE-AG549462A	PT Pancytopenia	Date:03/14/05ISR Humber: 4609761-XReport Type:Expedited (15-DaCompany Report #2005-DE-007766D	PT Depressed Level Of Consciousness Cxygen Saturation Decreased	Date:03/14/05ISR Number: 4609619-6Report Type:Direct
	pedited (15-DaCompany R	REPORT SOURCE	edited (15-DaCompany Re		Report Source	edited (15-DaCompany Ro	Report Source Literature	edited (15-DaCompany Re	Report Source	
	eport #PHBS2004JP17256	Welbutrin Sr Cogentin Trazodone Seroquel Klonopin Trilafon	port #US~GLAXOSMITHKLI	Cogentin Klonopin Trazodone Prolixin Seroquel	Product Wellbutrin Sr Lithium	port #US-GLAXOSMITHKLIN	Product DicLofenac (DicLofenac) (Nr) (DicLofenac Sodium) Quetiapine (Quetiapine) (Nr)	port #2005-bE-00776GD	Product Quetiapine Methadone Hydrochloride	Company Report #CTU 243102
		\$ 22 22 22 22 22 22 22 22 22 22 22 22 22	NE-A0549,	វ ល ល ល ល	Role PS SS	IE-A0549	Role PS		Role PS	
			464A Manufacturer		Manufacturer Glaxosmithkline Glaxosmithkline	462A	Manufacturer		Manufacturer	
	Age:72 YR	ORAL	Age: Route		Route ORAL	Age:	Route	Age:44 YR	Route	Age:30 YR
	Gender: Female		Gender: Dose		Dose	Gender:	Dose	Gender:Female	100 MG	Gender:Male
Page: 1227	ale I/FU:F		Duration		Duration	I/FU:I	Duration	le I/FU:I	natarran	I/FU:I

Freedom Of Information (FOI) Report Pharmaceuticals SS SS

Loxonin Mobic

ORAL ORAL ORAL

Date:08/04/05ISR Num Outcome Other	Date:03/04/D5ISR Numl Outcome Other			Initial or Prolonged	Date:08/03/05ISR Numbe
Date:08/04/05ISR Number: 4734602-XReport Type:Expedited (15-DaCompany Report #2005UW11346 Outcome PT Report Source Product Cyanosis Neonatal Other Drug Exposure During Premature Baby	Date:08/04/0515R Number: 4734125-8Report Type:Expedited (15-DaCompany Report #2005UW11176 Outcome PT Report Source Product Hypotension Other Loss Of Consciousness Unspecified 5 Lithobid Klonopin	Circulation Circulation PROFIABLE SKin Disciloration Skin Exfoliation Skin Exfoliation Skin Haemorrhage Spin Haemorrhage Spindal Ifeation Tongue Biring Tooth Disorder	Drug Withdrawal Syndrome Drug Withdrawal Syndrome Flushing Gallbladder Operation Hypomania Hemory Impairment Memory Impairment Memory Impairment	Amenorrhoea Blood Cholesterol Increased Bruxism Candidlasis Condition Aggravated Dermatiris Exfoliative	Date:08/03/05ISR Number: 4738261-lReport Type:Expedited (15-DaCompany Report #HQWYEZ4012ZHAR05 Outcome PT Report Source Product Consumer Efexor X:
pedited (15-DaCompany Rep Report Source	pedited (15-DaCompany Rep Report Source				adited (15-DaCompany Repo Report Source Consumer
ort #2005UW11346 Product Seroquel	ort #2005UW11176 Product Seroquel Hethadone Unspecified Sari Lithobid Klonopin	Heuronin (Gabapentin) Valium (Diazepam) Valium (Diazepam) Asnax (Alprasolam) Pariet (Rabepracole) Renitec (Enalapril Haleate) Di-Gesic (Dextropropoxyphene/ Paracetamol) Pethidine (Pethidine) Vitamins (Vitamins)	Hydrochloride, Tablet) Seroquel (Quetiapine)	(Venlafaxine Hydrochloride, Capsule, Extended Release)	rt #HQWYE24012ZMAR05 Product Efexor Xr
Role PS	Ro Le	0000 0 000	ts ts	Sq	Role
Manufacturer Zeneca Pharmaceutical	Manufacturer Zeneco Phørmaceutical				Manufacturer
Age:1 DY Route ORAL	Age:53 YR Route ORAL		ORAL ORAL	ORAL	Age:53 YR Route
Gender:Male Dose	Gender:Female Dose		37.5 MG 1X PER 1 DAY ORAL 100 MG 1X PER 1 DAY ORAL	150 MG 1X PER 1 DAY ORAL: 75 MG1X PER 1 DAY ORAL	Gender:Female Dose D
T/FU:I Duration 186 DAY	I/FU:I Duration		2 WK	1 WK	I/FU:F Duration

Death	Date:09/26/05TSR	Date:09/26/05ISR Outcome Death	Outcome Death	Date:09/26/05ISR Numb Outcome Date:09/26/05ISR Numb Date:09/26/05ISR Numb Initial or Prolonged Initial or Prolonged
Cardio-Respiratory Arrest Completed Suicide	Date:09/26/05ISR Number: 4780437-lReport Type:Expedited (15-DaCompany Report #2005127620 Outcome	Date:09/26/05ISR Number: 4780436-XReport Type:Expedited (15-DaCompany Report #20012/4/4 Outcome PT Report Source Product PT Literature Literature (Amiodipine Completed Suicide Health (Amiodipine) Drug Toxicity Professional Quetiapine Intentional Drug Overdose (Quetiapine)	er Cardiac Arrest Completed Suicide Drug Toxicity Intentional Drug Misuse Overdose Respiratory Arrest	
rŧ	pedited (15-DaCompany	adited (15-DaCompany Report Source L. Literature Health Professional	Report Source Literature Health Professional	ited (15-DaCompany Re Report Source Report Source Report Source Report Source
	Report #2005127620	Report #ZUUJIZ/4/Z Product Amlodipine (Amlodipine) Quetiapine (Quetiapine)	Alprazolam (Alprazolam) (Alprazolam) Wethadone (Methadone) Quetiapine Quetiapine) All Other Therapeutic Products (All Other Therapeutic	port #2005UM13844 Product Seroquel Aspirin Product Depakote Risperidone Risperidone Risperidone Quetiapine Quetiapine Quetiapine Product Product
		Role Manufacturer PS SS	S S S S S	Role Manufacturer PS Zeneca Pharmaceutical C Pharmaceutical S S S S S S S S S S S S S S S S S S S
	Age:	Route ORAL ORAL		Route ORAL Age: Route Route
	Gender:Unknown	Dose ORAL ORAL		Dose Di
Page: 1429	nowh I/EU:I	Duration	1/21/1	Duration I/FU:I Duration I/FU:I Duration

Outcome Death	Date:10/04/05IS	Other		Date:10/04/05IS		Outcome Other	Date:10/04/05ISI			Outcome	Date:10/04/05ISR	Other	Outcome	Date:10/04/05ISR	Outcome Other	Date:10/04/05ISR
PT Multiple Drug Overdose	Date:10/04/05ISR Number: 4789051-5Report Type:Expedited (15-DaCompany Report #DSA_27143_2005	Migraine	PT	Date:10/04/05ISR Number: 4788231-2Report Type:Direct		PT Bulimia Nervosa	Date:10/04/0515R Number: 4787071-8Report Type:Expedited (15-DaCompany Report #2005AC01292			PT Corebrovascular Accident	Date:10/04/05ISR Number: 4787065-2Report Type:Expedited (15-DaCompany Report #2005SE05479	Indelanda State Confusional State Ryperhidrosis Ryperhidrosis Rypotension Metabolic Acidosis Pheumonia Renal Failure Acute	PT Notice States	nate:10/04/05ISR Number: 4787063-9Report Type:Expedited (15-DaCompany Report #2005UW14398	PT Urticaria	Date:10/04/05ISR Number: 4787052-4Report Type:Expedited (15-DaCompany Report #RO-JNJFOC-20050900860
Report Source Literature Health Professional	dited (15-DaCompany		Report Source			Report Source	dited (15-DaCompany i			Report Source	dited (15-DaCompany F		Report Source	ited (15-DaCompany R	Report Source	ited (15-DaCompany R
Product Lorazepam Quetlapine Acetaminophen Pm	Report #DSA_27143_2005	Seroquel 25mg Astra Zeneca		Company Report #CTU 259464	Depakine Maniprex Seroxat	Product Seroquel	Report #2005AC01292	Lasix (Eurosemide)	Lapoxin	Product Seroquel	teport #2005SE05479	Methadone Maintenance	Product Seroquel	eport #20050W14398	Product Quetiapine Seroquel	eport #RD-JNJFOC-2005090
Role SS		s	Role		ឧក។	Role PS		n I	n	Role PS		n	Role PS		Role PS SS	0860
e Manufacturer		Astra Zeneca	Manufacturer			Manufacturer Zeneca Pharmaceutical						Pharmaceutical	Manufacturer Zeneca		Manufacturer	
Route ORAL ORAL ORAL	Age:32 YR	ORAL	Route	Age:27 YR	ORAL ORAL ORAL	Route	Age:488 MO		ORAL	Route OBAL	Age: 29420	ORAL	Route	Age:42 YR	Route ORAL ORAL	Age:
Dose DE UNK PO DE UNK PO	_	25MG ONCE DAILY PO	Dose	n		Oso	MON Gender: Female	DAILY 25 MG	TIMES A DAY 0.125 MG	Dose 25 MG THREE	Age:29420 DYGender:Female		Dose	Gender:Female	Dose	Gender:Male
Duracion	I/FU:I		Duration			Ed a r F C c			62 DAY	Duration			Duration	1/FU:I	Duration 28 DAY 28 DAY	I/FU:I

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FDA - Adverse Event Reporting System (AERS)

Outcome Death	Date:10/05/05ISR Numbe	Outcome Death	Date:10/05/05ISR Numbe	Outcome Hospitalization - Initial or Prolonged	Date:10/05/05ISR Numbe	Date:10/05/05ISR Number Outcome Required Intervent Fermanent Impairment/Damage
PT Cardio-Respiratory Arrest Completed Suicide Multiple Drug Overdose	Date:10/05/05ISR Number: 4791975-XReport Type:Expedited (15-Dacompany Report #DSA_70811_2005	PT Completed Suicide Multiple Drug Overdose	Date:10/05/05ISR Number: 4790676-IReport Type:Expedited (15-DaCompany Report #DSA_70812_2005	PT Agitation Hypotension Overdose Somnolence Tachycardia	Date:10/05/05ISR Number: 4790135-6Report Type:Direct	Feeling Jittery Gait Disturbance Headache Syncope Tremor Premor Prem
Report Litera Health Profes	ted (15	Report Sou: Literature Health Profession	ted (15-	Report		Report Source Compa
Report Source Literature Health Professional	-DaCompany Rep	Report Source Literature Health Professional	-DaCompany Rep	Report Source	Company Rep	Report Source Company Repo
Product Methadone Quetiapine Alprazolam	ort #DSA_70811_2005	Product Methadone Queriapine Citalopram	ort #DSA_70812_2005	Product Seroquel	Company Report #CTU 259695	ource Product Quetiapine 100 Mg Lamotrigine Fluoxetine Clonazepam Apap Product Blaxin 500mg Seroquel 100mg Daily Accuchecks Provacid Doxycycline Foamax Lavaquin Levothyroxine One-Tab Daily Vitamins Seroquel Zolofft Zolofft
Role PS SS		Role PS SS SS		PS Role		PS CCCCCCCCCCCCCCCCCCCCCCCCCCCCCCCCCCCC
Manufacturer		Manufacturer		Manufacturer		Manufacturer Manufacturer
Route ORAL ORAL ORAL	Age: 42 YR	ROUTE ORAL ORAL ORAL	Age:43 YR	Route	Age:	Route ORAL Age: Route ORAL OPAL
DE UNK PO DE UNK PO DE UNK PO	Gender:	Dose Of 30 Of 30	Gender:	розе	Gender:Male	Dose 100 MG PO Gendex: Female Dose 500MG BID PO 250MG TID PO
DUFACTOR	I/FU:I	Duration	1/50:1	Durathon	I/FU:I	PO Duration Female I/FU:I Duration BID PO 14 DAY TID PO

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

Outcome Hospitalization - Initial or Prolonged	Date:10/06/05ISR Numbe	Date:10/06/05TSR Number Outcome Hospitalization - Initial or Prolonged	Other	Date:10/06/0515R Number	Date:10/06/05ISR Number Outcome Other	Date:10/06/05ISR Number Ourcome Hospitalization - Initial or Prolonged	Date:10/05/05ISR Number: Outcome Death
PT Alcohol Usc Electrocardiogram Qt Prolonged	Date:10/06/05ISR Number: 4789827-4Report Type:Expedited (15-DaCompany Report #2005018344	Date:10/06/D5ISR Number: 4789675-5Report Type:Expedited (15-DaCompany Report #20055E05495 Outcome PT Report Source Product Hospitalization - Schizophrenia Initial or Prolonged Ouetiapine	Intentional Self-Injury Libido Incressed	Date:10/06/05i5k Number: 4789667-6Report Type:Expedited (15-DaCompany Report #2005AP02307	Date:10/06/05ISR Number: 4789564-6Report Type:Expedited (15-DaCompany Report #2005UW14702 Outcome PT Report Source Product White blood Cell Count Seroquel	Date:10/06/05ISR Number: 4789478-1Report Type:Expedited (15-DaCompany Report #2005UW14771 Ourcome PT Report Source Product Hospitalization - Overdose Seroquel	Date:10/05/05ISR Number: 4793351-2Report Type:Expedited (15-DaCompany Report #DSA_70816_2005 Outcome PT Report Source Product Outcome Cardio-Respiratory Arrest Literature Methadone Death Multiple Drug Overdose Health Zolpidem
	edited (15~DaCompany R	edited (15-DaCompany Re Report Source		dited (15-DaCompany Re	dited (15-Dacompany Rej Report Source	dited (15-DaCompany Rep Report Source	dited (15-DaCompany Rer Report Source Literature Health Professional
	eport #2005018344		Quetiapine Quetiapine Loracepam Moclobemide Moclobemide Moclobemide Molbrenide Temazepam Multivite Six Pamol	port #2005AP02307	port #2005UW14702 Product Seroquel	oort #2005UW14771 Product Seroquel	oort #DSA_70816_2005 Product Methadone Zolpidem Quetiapine
		Role PS	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	Role	Role PS	Role	Role PS SS
		Manufacturer Zeneca Pharmaceutical Zeneca Pharmaceutical		Manufacturer	Manufacturer Zeneca Pharmaceutical	Manufacturer Zeneca Pharmaceutical	Manufacturer
	Age:45 YR	Age:12356 Route ORAL ORAL	ORAL ORAL ORAL ORAL ORAL ORAL	Age:12736 Route	Age:667 MON Route ORAL	Age: Route ORAL	Age:46 YR Route ORAL ORAL ORAL
	Gender:Female	DYGender:Female Do⊴e	AS REQUIRED AT NIGHT 2 TABLETS 1 - 2 TABLETS ONE TABLET J-4 TIMES DAILY	DYGender:Female Dose	N Gender:Female Dose	Gender:Male Dose	Gender: Dose DF, PO PO DF PO
Page: 1449	e I/fU:F	e I/FU:I Duration	rs 4 Mon	1/FU:F Duration	I/FU:I Duration	I/FU:I	I/FU:I Duration

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Outcome Death	Date: 10/06/05Is	Outcome Death	Date:10/06/05IS	Outcome Death	Date:10/06/05Is	Outcome Death	Date:10/06/05IS	Death	Date:10/06/0515F	Outcome Death	Date:10/06/05ISF
PT Completed Suicide Multiple Drug Overdose	Date:10/06/05ISR Number: 4793543-2Report Type:Expedited (15-DaCompany Report #AND_0080_2005	PT Completed Suicide Multiple Drug Overdose	Date:10/06/05ISR Number: 4793522-5Report Type:Expedited (15-DaCompany Roport #FAR_0270_2005	PT Completed Suicide Multiple Drug Overdose	Date:10/06/05ISR Number: 4793451-7Report Type:Expedited (15-DaCompany Report #AND_0188_2005	PT Hultiple Drug Overdose	Date:10/06/05ISR Number: 4792036-6Report Type:Expedited (15-DaCompany Report #PAR_0223_2005	Completed Sulcide Intentional Drug Misuse Multiple Drug Overdose	Date:10/06/05ISR Number: 4792029-9Report Type:Expedited (15-DaCompany Report #PAR_0311_2005 Outcome PT Report Source Product	PT Completed Suicide Multiple Drug Overdose	Date:10/06/05ISR Number: 4792026-]Report Type:Expedited (15-DaCompany Report #PAR_0219_2005
Report Source Literature Health Professional	edited (15-DaCompany F	Report Source Literature Health Professional	edited (15-DaCompany R	Report Source Literature Health Professional	edited (15-DaCompany R	Report Source Literature Health Professional	edited (15-DaCompany R	Health Professional	dited (15-DaCompany Report Source	Report Source Literature Health Professional	dited (15-DaCompany Re
Product Acetaminophen W/Propoxyphene Propranolol Quetiapine	Report #AND_0080_2005	Product Fluoxetine Quetiapine Methanol	cport #PAR_0270_2005	Acetaminophen Acetaminophen W/Propoxyphene Quetiapine Unknown Chemical	eport #AND_0188_2005	Froduct Citalopram Phenobarbital Quetiapine	eport #PAR_0223_2005	Acetaminophen W/Propoxyphene Quetiapine	port #PAR_0311_2005 Product Propranolol	Product Citalopram Methadone Queliapine	port #PAR_0219_2005
Role Manufacturer PS SS		Role Manufacturer PS SS SS		S S S S S S S S S S S S S S S S S S S	oole Kannfacturet	Role Manufacturer PS SS SS		in in	Role Manufacturer PS	Role Manufacturer PS SS SS	
Route	Age:37 YR	Route ORAL ORAL ORAL	Age:22 YR		Age:73 YR Route	Route ORAL ORAL ORAL	Age:19 YR	ORAL ORAL	Age:3/ YK Route ORAL		Age:43 YR
DF DF:	Gender:	DE PO DE PO DE PO	Gender:	0F 0F 0F	Gender:	Dose DE UNK PO DFUNK PO	Gender:	DE UNK PO	Dose DF UNK PO	Dose DE UNK PO DE UNK PO	Gendor:
Duration	I/FU:I	DUEGETON	I/FU:I		I/FU:I Duration	Duration	I/FU:I		Duration	Duration	1/FU:I

Outcome If Outcome Instonia Instonia Instructionia Neurolep Syndrome Oculogy	Date:10/13/05ISR Number: 4797325-7Report Type:Expedited (15-DaCompany Report #2005UW14478	Outcome PT Hospitalization - Schiz Initial or Prolonged	Date:10/13/05ISR Number: 4796877-OReport Type:Expedited (15-DaCompany Report #2005SE04172	Outcome Blood Protest Blood Protest Bradycar Intention Overdose	/12/05ISR Number:					Hental Hental	Outcome PT Death Ammoni	Date:10/12/05TSR Number: 4800344-5Report Type:Expedited (15-DaCompany Report #2005-BP-12458RO	Overdose Suicide Treatmen	or Prolonged	Outcome	Date:10/12/05I5R Number: 4799980-4Report Type:Direct
PT Vystomia Neuroleptic Malignant Syndrome Oculogyric Crisis	325-7Report Type:Expedi	PT Schizophrenia	877-OReport Type:Expedit	Blood Pressure Decreased Bradycardia Intentional Drug Misuse Overdose	236-8Report Type:Expedit					Mental Status Changes	PT Ammonia Increased	44-5Report Type:Expedite	Overdose Suicide Attempt Treatment Noncompliance	Biepharospasm Cerebrovascular Accident Facial Palsy Hypoaesthesia Oral		80~4Report Type:Direct
	ted (15-DaCompany Repor	Report Source	ed (15-DaCompany Repor	Foreign Health Professional	ed (15-DaCompany Report Report Source	,					Report Source Health Professional	ed (15-DaCompany Report			Report Source	Company Report #CTU 260490
	t #2005UW14478	Product Quetiapine	L #2005SE04172	Nardil (Phenelzine Sulfate) Atenolol (Atenolol) Seroquel (Quetiapine Fumarate)	Product		Xeloda (Capecitabine)	Lexapro (Escitalopram Oxalate)	Seroquel (Quetiapine Fumarate)		Product Mechadone Hcl Tablets Usp, 10 Mg	#2005-BP-12458RO		ine-	Product	#CTU 260490
		PS NOTE		S CS CS	Role		C	ts ts	S.	PS	Role			Sd	Role	
		Zeneca Pharmaceutical			Manufacturer						Manufacturer			Astrazeneca	Manufacturer	
	Age:64 YR	ORAL.	Age:8874 D)	ORAL ORAL		Acc:54 YR		ORAL	OFAL	ORAL	Route	Age:		ORAL	Route	Age:27 YR
	Gender:Male		Age:8874 DY Gender:Female	800 MG, ORAL ORAL 75 MG, ORAL	Dase	Gender:Female		10 MG/DAY PO 1 TO 2 WEEKS	125 MG QHS PO 1 TO 2 WEEKS	5 MG BID (5 MG), PO 1 TO 2 WEEKS	DOM	::Female		PO BID	Dose I	Gender:Male
Page: 1459	I/FU:F	178 DAY	I/EU:E		Duration	1/EU:I			J	-		1/FU:1			Duration	I/FU:I

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Other Other	Date:11/14/05ISR Nun	Date:11/14/05ISR Num Outcome Other	Date:11/14/05ISR Num Outcome Death	Date:11/14/05ISR Number: Outcome Death	Other	Outcome Hospitalization - Initial or Prolonged	Date:11/14/05ISR Numb
Diabetes Mellitus Diabetes Control Drug Effect Decreased Glycosylated Haemoglobin Increased	Date:11/14/05ISR Number: 4827852-5Report Type:Direct	Date:11/14/05ISR Number: 4827586-7Report Type:Expedited (15-DaCompany Outcome PT Other Diabetes Mellitus	Date:11/14/051SR Number: 4827585-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20051102786 PT Report Source Product P. Outcome Adverse Event P. Death Seroquel S	per: 4827556-9Report Type:Expedited (15-DaCompany Report #2005UW15509 PT Report Source Product Drug Interaction Pago Inhibitor Road Traffic Accident Westhadone	Consciousness Hypotension Loss Of Consciousness Tachycardia Wrong Drug Administered	PT Accidental Overdose Depressed Level Of	Date:11/14/05ISR Number: 4827267-XReport Type:Expedited (15-DaCompany Report #2005ACD1745
	7	ited (15-DaCompany Repo Report Source	ted (15-DaCompany Repo Report Source	ted (15-DaCompany Repo Report Source		Report Source	ted (15-DaCompany Repc)
Quetiapine 75 Mg Acetaminophen Claforan Albuterol Cleocin Amlodipine Levaquin Budesonide Zosyn Enalapril Epoetin Iprotropium Lansoprazole Heparin	Company Report #CTU 262965	Report #US~JNJFOC-20051102788 Product R Product R Alsperdal S Zyprexa S Seroquel S	rt #US-JNJFOC-20051102 Product Risperdal Ability Seroquel	rt #2005UW15509 Product Seroquel Mao Inhibitors Methadone	Oseltamivir Hydrocodone Cough Syrup	Product Seroquel	ct #2005AC01745
	Role	Role PS SS SS	786 Role PS SS	Role PS	c ss	Role PS	
	Manufacturer	Manufacturer	Manufacturer	Manufacturer Zeneca Pharmaceutical		Manufacturer Zeneca Pharmaceutical	
CKALL	Age:88 YR	Age: Route	Age: Route	Age: Route		Route	Age:8 YR
		Gender:Female Dose	Gender:Male Dose	Gender: Dose	DRUG USUALLY PRESCRIBED.		::Male
NON 9	I/FU:I	1/FU:1 Duration 27 MON 27 MON 27 MON 27 MON	I/FU:I Duration 22 MON 22 MON 22 MON 22 MON	1/FU:F Duration		Duration	I/FU:1

Outcome Death	Date:11/14/05TSR Num			Death	Outcome	Date:11/14/05ISR Num			Outcome Death		nate:11/14/0515R Numi			Death	Outcome	Date:11/14/05ISR Numb		Other	Outcome	Date:11/14/05ISR Numb	
PT Completed Suicide Multiple Drug Overdose	Date:11/14/05ISR Number: 4030359-2Report Type:Expedited (15-DaCompany Report מיניטראבייטיא		מוספרמוורפ השומפי	Completed Suicide Multiple Drug Overdose Intentional	PT	Date:11/14/05ISR Number: 4830011-3Report Type:Expedited (15-Dacompany Report #2005A1004089	Respiratory Arrest	Multiple Drug Overdose	Cardiac Arrest	T T T T T T T T T T T T T T T T T T T	nsra.117/14/05TSR Number: 4830004-6Report Type:Expedited (15-DaCompany Report #2005AL004224		intentional	Multiple Drug Overdose	PT	Date:11/14/d5ISR Number: 4830002-2Report Type:Expedited (15-DaCompany Report #2005AL004225	Somnolence Wrong Drug Administered	Medication Error	PT	Date:11/14/05ISR Number: 4827923-3Report Type:Direct	
Report Source Literature Health Professional	lited (15-DaCompany Ke			Health Professional	Report Source	ited (15-DaCompany Re		Professional	Literature Health	Report Source	ited (15-DaCompany Re)			Health Professional	Report Source	ted (15-DaCompany Rep			Report Source	Company Rep	
Product Verapamil Hydrochloride Tablets, 120 Mg [Purepacl Valproic Acid Quetiapine	Sport Mycoopposite	#3005Y100A110	Mg/650 Mg (Purepac) Quetiapine Unknown Chemical	Napsylate And Acetaminophen Tablets Usp, 100	Product	port #2005AL004069		Methadone Queciapine	Alprazolam Tablets Usp, 2 Mg (Purepac)	Product	port #2005AL004224	Quetrapine	(Purepac) Methadone	Hydrobromide Tablets, 40 Mg	Product Citalopram	ort #2005AL004225		Seroquel	Product Sineguan	Company Report WUSE 3/410	
Role Manufactures			S S S		Role Manufacturer			ស ស ស	PS	Role Manufacturer		v	SON		Role Manufacturer			SS Astrazeneca	Role Manufacturer PS Pfizer		
ORAL ORAL		Age:38 YR			Route	Age:73 YR		ORAL	ORAL	Route	Age:42 YR		ORAL ORAL	}	Route	Age:43 YR			Roune	,	Age:
0 O G	Dase	Gender:			Dose	Gender:		Od	8 8	Dose	Gender:Unknown	,	9 8 8 8 8 8	3	Dose	Gender:Unknown		10000	CAPSULE	,	Gender:
	Duration	1/50:1			puration	I/FU:I				Duration	own I/FU:I				Duration	own 1/FU:I				+	1/FU:1

Freedom Of Information (FOI) Report

Respiratory Affect Substance Abuse	Outcome PT Cardiac Arrest	Date:11/18/05TSR Number: 4833811-9Report Type:Expedited (15-DaCompany Report #2005-BP-19395RO	Outcome GATAIAC Arrest Death Completed Snicide Multiple Drug Overdose Intentional Respiratory Arrest	Datc:11/18/05ISR Number: 4833793-KReport Type:Expedited (15-DaCompany Report #2005-BP-19469RO	Date:11/18/05ISR Number: 4831344-7Report Type:Expedited (15-DaCompany Report #2005R02140 Outcome
	Report Source St Literature	port Type:Expedited (15-DaCo	Report Source Literature icide Health y Overdose Professional	oort Type:Expedited (15-DaCon	It Type:Expedited (15-DaCompan Report Source Lon potension potension Report Source tension St Source Report Source tension St Source Lar Block t Source Source Source Lar Block t Source Report Source Report Source Lar Block t Source Report Sou
	rce Product Cocaine (Cocaine) Quetiapine	mpany Report #2005-BP-19395RO	rce Product Methadone Alpracolam Intensol [Oxal Soluttion [Concentrate]] 1 Mg/H1 (Alpracolam) Quetiapine [Quetiapine]	npany Report #2005-BP-19469RO	any Report #2005PK02140 Product Seroquel Seroquel Seroquel Seroquel Listeria Seroquel Seroquel Product Seroquel Seroquel Seroquel Seroquel Seroquel Seroquel Seroquel Obiazepam Diszepam Clonazepam Temazepam Verapamil Sr Quetiapine
ហ	Role Manufacturer PS		SS SS SOLD MAINTENANCE STATE S		Role Manufacturer PS Zenece Pharmaceutical C C C T Role Manufacturer PS Zeneca Pharmaceutical
	2000	Age: 48 YR		Age:42 YR	Age: 45 YR ORAL ORAL ORAL Age: 66 YR Route ORAL ORAL Age: 45 YR Route URKNOWN URKNOWN UNKNOWN
		Gender:		Gender:Unknown Dose Di	Dose Gender: Hale Dose Dose Dose
Page: 1508		I/FU:I Duration		own I/FU:I Duration	Duration 63 DAY 12 DAY 12 DAY 17FU:I Duration Duration Duration

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

PT Report Source Product Role Manufacturer Route Doss	te:11/18/05TSR Number: 4833824-7Report Type:Expedited (15-DaCompany Report #2005-RP-1947GRO Age:43 YR Gendi	Gabapentin (Gabapentin) 55
1te	Age:43 YR	
Dose	Gender:	
Duration	I/FU:I	

Outcome Life-Threatening Hospitalization - Initial or Prolonged	Date:11/18/05ISR Numbe	Outcome Death	Date:11/18/05ISR Numbe	Outcome Death	Date:11/18/05ISR Numbe	Outcome Doath	Date:11/18/05fSR Numbe
PT Abnormal Behaviour Aggression Bipolar Disorder Drooling Gait Distrubance Increased Apoetite Intelligence Test Abnormal Mental Retardation Baralysis Starling Face Tongue Disorder Tremor Meight Increased	Date:11/18/0515R Number: 4833940-XReport Type:Direct	PT Completed Suicide Multiple Drug Overdose Incentional	Date:11/18/05ISR Number: 4833917-4Report Type:Expedited (15-DaCompany Report #2005-BP-19734RO	PT Cardiac Arrest Respiratory Arrest	Date:11/18/0515R Number: 4833833-8Report Type:Expedited (15-DaCompany Report #2005-8P-19474RO	PT Completed Suicide	Date:11/18/05/SR Number: 4833824-TReport Type:Expedited (15-DaCompany Report #2005-RP-19470RO
Report Source		Report Source Literature Health Professional	ted (15-DaCompany Re	Report Source Literature Health Professional	ted (15-DaCompany Re	Report Source 1lterature Health Professional	ed (15-DaCompany Kep
Risperdal Seroquel Benadryl Duppkote Viracept Eprvir Zerit	Company Report #CTU 263437	Product Diclofenac (Diclofenac) (Diclofenac) Quetiapine (Quetiapine) Simvastatin (Simvastatin)	port #2005-8P-19734RO	Product Methadone (Methadone) Zolpidem (Zolpidem) Quetiapine (Quetiapine)	poit #2005-BP-19474RO	Methadone (Methadone) Citalopram (Citalopram) Quetiapine (Quetiapine)	oort #2005-RP-19470RO
G G G G G S S S S S S S S S S S S S S S		ROLD MANUFACCURER PS SS SS		Role Manufacturer PS SS SS		63 153 TO 15	Role Manifaction
•	Age:14 YR	Source	Age:60 YR	Route	Age:46 YR		Age:43 YR
(?UNSURE) 300MG DATLY	Gender:Male	50.00	Gender:	Dose	Gender:		Gender:
	1/FU:I		I/FU:I	Duracion	I/FU:I		I/FU:I Duration

Date:12/30/05ISF Outcome Other	Date:12/30/05ISR Outcome Other	Date:12/30/05ISR Num Outcome Hospitalization - Initial or Prolonged	Date:12/29/0515R Outcome Death	Outcome Death	Date:12/29/05ISR	Date:12/29/05ISR Outcome Death
Date:12/30/05ISR Number: 4869353-4Report Type:Expedited (15-DaCompany Report #2005UW19309 Outcome PT Report Source Product Other Retinal Haemorrhage	Date:12/30/0515R Number: 4869165-1Report Type:Expedited (15-DaCompany Report #2005DW19251 Outcome FT Report Source Product Other Blindness Unilateral Lithium	Date:12/30/05ISR Number: 4869164-XReport Type:Expedited (15-DaCompany Report #2005UW19391 Dutcome PT Report Source Product Hospitalization - Cardiac Arrest Seroquel Initial or Prolonged Convulsion	Date:12/29/05ISR Number: 4871445-0Report Type:Expedited (15-DaCompany Report #MK200512-0499-1 Outcome Product Report Source Product Literature Methadose@ Methad Cardiac Arrest Literature Hy Oral Con Usp Multiple Drug Overdose Health Hy Oral Con Usp Respiratory Arrest Professional Zulpidem Quetiapine	PT Completed Suicide Multiple Drug Overdose Intentional	Date:12/29/05ISR Number: 4871317-lReport Type:Expedited (15-Dacompany Report ∦MKZ00512-0492-1	Date:12/29/05ISR Number: 4871313-4Report Type:Expedited (15-DaCompany Report #MK200512-0489-1 Outcome FT Report Source Product Death Cardiac Arrost Literature Methadose Methado Death Completed Suicide Health Multiple Drug Overdose Professional Quetiapine Titentional Respiratory Arrest Respiratory Arrest
pedited (15-DaCompany R Report Source	aedited (15-DaCompany R Report Source	edited (15-DaCompany Re Report Source	edited (15-DaCompany Re Report Source Literature Haalth Professional	Report Source Literature Health Professional	edited (15-DaCompany Re	edited (15-DaCompany Re Report Source Literature Health Professional
eport #2005UW19309 Product Seroquel	eport #2005UW19251 Product Seroquel Lithium	port #2005UW19391 Product Seroquel Prolixin	port #MK200512-0499-1 Product Methadose@ Methadone Hy Oral Con Usp Zolpidem Zoupthen Quethapine	Product Methadose Methadone Hy Oral Con Usp Quetiapine Citalopram	port #MK200512-0492-1	port #HK200512-0489-1 Product Methadose Methadone Hy Oral Con Usp Quetlapine Alprazolam
Role PS	Role PS	Role PS	e Role FS SS	Role PS SS		Rolc PS SS
e Manufacturer Zeneca Pharmaceutical	Manufacturer Zeneca Pharmaceutical	. Manufacturer Zeneca Pharmaceutical	Manufacturer	Manufacturer Usp		Hanufacturer Usp
Age: /2 In	Age:17 YR Route ORAL	Age:34 YR Route ORAL	Age:46 YR Route ORAL	Route ORAL	Age:43 YR	Age:42 YR Route ORAL
Dose		Gender:Female Dose	Gender: Dose PO	PO e	Gender:Not Specifil/FU:I	Gender:Not Specifil/FU:I Dose Duration PO
Duration	e I/FU:I Duration I/FU:I	e 1/fU:I Duration	I/FU:l Duration	Duration	ecifil/fU:I	ecifil/FU:I Duration

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Outcome Death	Date:06/15/06ISF	Date:06/15/06ISR Outcome Neath	Date:06/15/061SR Outcome Death	Outcome Death	Date:06/15/06ISR	
PT Accidental Death Drug Toxicity	Date:06/15/0615R Number: 5026624-9Report Type:Expedited (15-DaCompany Report #2006AC01097	Date:06/15/06ISR Number: 5026623-TReport Type:Expedited (15-DaCompany Report #2006ACU1093 Outcome PT Report Source Product Completed Suicide Seroquel Drug Level Above Bupropion Therapeutic Carbamazepine Drug Toxicity Diphennydrami	Date:06/15/061SR Number: 5026622-5Report Type:Expedited (15-DaCompany Report #2006ACD1092 Outcome FT Report Source Froduct Secoquel Drug Level Above Valproic Acid	PT Completed Suicide Drug Toxicity Multiple Drug Overdose Intentional	Date:06/15/06IGR Number: 5026621-3Report Type:Expedited (15-DaCompany Report #2006AC01090	
Report Source	pedited (15-DaCompany Ro	pedited (15-DaCompany Re Report Source	pedited (15-DaCompany Re Report Source	Report Source	edited (15-DaCompany Rep	Report Source
Product Scroquel Methadone Nortriptyline Fluowetine Diazepam Nordiaz	eport #2006AC01097	port #2006AC01093 Product Seroquel Bupropion Carbamazepine Diphenhydiamine	port #2006ACD1092 Froduct Seroquel Valproic Acid	Product Seroquel Paroxetine Loracepam Valproic Acid Trimethoprim	port #2006AC01090	Product Seroquel Seroquel Aricept Temazepan Pravachol
SSS SS		PS PS SS SS	Role PS	Role PS SS SS SS		CCC SS PS Le
. Manufacturer Zeneca Pharmaceutical		Hanufacturer Zeneca Pharmaceutical	Manufacturer Zeneca Pharmacoutical	Manufacturer Zeneca Pharmaceutical		Manufacturer Pharmaceutical Zeneca Pharmaceutical
Route ORAL	Age:46 YR	Age:18 VR Route ORAL	Age:34 YR Route ORAL	Route	Age:30 YR	Route ORAL ORAL ORAL ORAL ORAL ORAL
Dose	Gender:Male	Gender:Male Dose	Gender:Male Dose	Dose	Gender:Female	Dose
Duration		I/FU:I Duration	I/EU:I Duration	Duration	e I/FU:I	Duration

		Freedon	Freedom Of Information (FOI) Report	Report				
Dare:06/22/06ISB Numb	Darm: 06/72/06ISB Number: 5032799-BReport Type:Expedited (15-DaCompany Report #2006UW12982	dited (15-DaCompany Rep	port #2006UW129B2			Age:58 YR	Gender:Malo	1/FU:1
Outcome	Tu	Report Source	Product	Role	Manufacturer	Route	Dase	Duration
Death	Completed Suicide Suicide Attempt		Seroquet	70	Pharmaceutical	ORAL		
Critica			Seroquel	S S	Zeneca Pharmaceutical	ORAL		
			Prozac	n	LHOTHOCOCCIC	i		
			Prilosec Nitroglycerin	n n				
Date:06/22/06ISR Numb	Date:06/22/06ISR Number: 5032818-9Report Type:Expedited (15-DaCompany Report #2006UW05682	edited (15-DaCompany Rep	port #2006UW056B2			Age:53 YR	Gender:Female	1/FU:F
	E-a	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization -	Blood Sodium Decreased	-	Seroquel	PS	Zeneca	0821		
Initial or Frolonged	Condition Aggravated Convulsion		Cogentin	С	Fnarmaceuricai	ORAL		
	Hypertension Lethargy Nourcleptic Malignant							
	Syndrome Pyrexia							
	Increased							
Date:06/22/06ISR Numi	Datn:06/ZZ/06ISR Number: 503Z819-0Report Type:Expedited (15-DaCompany Report #2006UW12482	edited (15-DaCompany Re	port #2006UW12482			Age:34 YR	Gender:Female	e I/FU:I
Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypotension Overdose		Seroquel	מי	Zeneca Pharmaceutical	ORAL		
		patrod (15-Daromeany Re	DOTE #2005UM12593			Age:46 YR	Gender:Male	1/FU:1
Date. out the outon num	EBIE DOLY PLANTER TORREST TORR				•			To reat in
Outcome Other	Pyr Dysstasia	Report Source	Product Seroquel	Role PS	Manufacturer Zeneca Pharmaceutical	ORAL	Dose	Duracton
	Muscle Spasms		Seroquel	ES:	Zeneca Pharmaceutical	ORAL		
			Diabetes Fill Cogentin Prolixin Palexid	0000				
						Are-40 VR	Gender:	I/FU:I
Date:06/22/0615K Number:	Del: 3033140-/Reputt +ype.copentrac (12 bosonipary) refore Product	Delivet Source	Product	Role	Manufacturer		Dose	Duration
Hospitalization -	Drug Toxicity		Seroquel	rp SS	Zeneca Pharmaceutical	ORAL		
Initial or Prolonged				1	100000000000000000000000000000000000000	ORAL	30-40 MG	

Page: 1914					ļ			
			Zeneca	ស	Seroquel			
		ORAL	Zeneca Pharmaceutical	or or	Seroquel		Hepatic Steatosis	
		ORAL	Pharmaceutical	: :	Seroquet		Death Drug Toxicity	Death
001	0	Route	Manufacturer	Role	Product	Report Source	TG	Outcome
	Gender: Lewate	Age:36 IK			Report #2006UW16057	dited (15-DaCompany	Date:08/16/06ISR Number: S081881-BReport Type:Expedited (15-DaCompany Report #2006UW16057	Date:08/16/06ISR Numb
							Hypothermia	
		:		r	Risperidone		Phosphokinase Increased	
		ORAL		חר	Hydantol F		Blood Creatine	
		ORAL		n	Cercine		Aminotransierase Increased	
2 DAY		ORAL	Pharmaceutical	ú	Seroquel		Aspartate	
		Cicker	Zoneca				Increased	Coner
7 DAY		0031	Zeneca	Sa	Seroquel	Report Source	PT Alanine Aminotransferase	Outcome
Duration	Dose	Route	Manufacturer		Product	1		
I/FU:I	Gender:Male	Age:57 YR			leport #2006AP03775	Type:Expedited (15-DaCompany Report #2006AP03775	r: 5081740-Okeport Type:Exped	Date:08/16/06ISR Number: 5081740-OReport
		ORAL		n	Lendormin			
		ORAL		C	Amoban		Increased	
		ORAL		nı			White Blood Cell Count	
		ORAL		י כ	Wypax		Rhabdomyolysis	
		ORAL		າດ	Mailax		Malaise	
47 DAY		ORAL	Pharmaceutical		Seroquel		Phosphokinase Increased	
		ORAL	Pharmaceutical		,		Blood Creatine	
70 DAY			Zeneca	SS	Seroquel		Increased	
14 DAY		ORAL	Zeneca Pharmaceutical	73 173	Seroquel		Aminotransferase	
49 DAY		ORAL	Pharmaceutical				Arthropod Bite	
; <u>?</u>		i	Zeneca	SS SS	S TOOLS		Increased	Initial or Prolonged
16 DAY		ORAT.	Zeneca		Seroquel		Alanine Aminotransferase	Outcome
Duration	Dose	Route	Manufacturer	n	Product	Report Source		
1/FU:F	DY Gender:Female	Age:9683 DY			eport #2006AP03318	ited (15-DaCompany Re	naro-na/16/06158 Number: 5081048-3Report Type:Expedited (15-DaCompany Report #2006AP03318	nate.og/16/06TSR Numbe
				a r	Ritalin Depakote			
		ORAL	Pharmaceutical					
			Zeneca	SS Z	Seroquel			
		ORAL	Zeneca Pharmaceutical	SS P	Seroquel		Suicide Attempt	
		ORAL	Pharmaceutical		Seroquel		Intentional Overdose	
		URAL	Pharmaceutical		•		Administered	Tritial or Prolonged
			Zeneca	Sd Sd	Seroquel	Report Source	PT PT	Outcome
Duration	Dose	DOI: to					Date: UB/16/U615K Numder: Suervay - Anaport Africance	Date:08/16/0615K Number
I/FU:I	Gender:Male	Age:17 YR			port #2006UW15993	ted (15-DaCompany Re	1004041	

Prilosec Ampirin Report #2006UW16088 Product Scroquel Metoprolol Vistaril Altace Majnesium Citt Xanax Mcthadone Product Seroquel Depakote Product Seroquel Depakote Product Seroquel Depakote Product Seroquel Distraneurine Ebixa Seroquel Distraneurine Ebixa	Outcome Path Death Hospitalization - Alanine Aminotransferase Initial or Prolonged Increased Aspartate Aminotransferase Increased Bite Compulsions Death Dyskinesia Psychomotor Hyperactivity Sommolence	Drug Interaction Health Dyskinesia Professional Other (722/06ISR Number: 5085724-BReport Type:Expedited (15-DaCompany Report	Type:Expedited (15-DaCompany Report Report Source Foreign	Data:08/21/D6ISR Number: 5084602-BReport Type:Expedited (15-DaCompany Report #2006UW16386 Outcome PT Report Source Product Death Pancreatitis	or Prolonged Abnormal Cardiac Arrest Drug Interaction Electrocardiogram Ot Prolonged Hypothyroidism Torsade De Pointes	рег: 5084600-4Report Type:Expedited (15-Dacompany Report PT Report Source	eri: Aspi
		SS SS C C	Role PS	Role PS	наоооа	Ē.	ดก
3 5 6 Pe			Manufacturer	Manufacturer Zeneca Pharmaceutical	Pharmaceutical	Manufacturer Zeneca	
		ORAL ORAL Age:	Age:76 YR Route ORAL	Age:31 YR Route ORAL	ORAL	Age:50 YR Route	ORAL
Pharmaceutical ORAL ORAL ORAL ORAL ORAL ORAL ORAL ORAL		PO MG Q DAY PO Gender: Wale	Gender:Female Dose 1 MG Q DAY PO	Gender: Male Dose		Gender:Female Dose	
Age:50 YR Gender:Female Zeneca Pharmaceutical ORAL Age:11 YR Gender:Male Age:11 YR Gender:Male Age:11 YR Gender:Male Age:76 YR Gender:Female Dose Age:76 YR Gender:Female Age:76 YR Gender:Male	Page: 19	1/50:1	I/FU:I Duration	I/FU:I Duration 5 YR		I/FU:I Duration	

Medication Error	Outcome F1 Other Accidental Drug Intake By		Date:19/11/06TSR Number: 5124787-8Report Type:Expedited (15-DaCompany Report #2006UW19170	Distribance in Action. Hypersonnia Lethargy Mania Vomiting	normal Beh	Over the same	Dare:10/10/06ISR Number: 5126500-7Report Type:Expedited (15-DaCompany Report #2006104942							Pulmonary Oedema	Outcome PT Drug Toxicity	Date:10/10/06ISR Number: 5126494-4Report Type:Expedited his working out of the following the followi										Visceral Oedema	Pulmonary Oedema	Drug Toxicity		Outcome	
		Report Source	/pe:Expedited (15-DaCompany	וורידמו		Report Source	ре:Ехреdited (15-DaCompany h						Professional	Health	Report Source Literature	e:expentred transcompany .	n. Turnelited (15-DaCompany R											Professional	Health	Report Source	37)1:27
	Seroquel	Product	Report #2006UW19170	Paxil (Paroxetine Hydrochloride) Seroquel (Quetiapine Fumarale)	(Varencline)	Product	Report #2006104942	(Fluoxetine)	(Diazepam Injection) (Nortriptyline)	(Methadone) Nortriptyline	Methadone (Phenytoin Sodium Injection)	(Quetiapine)	Ouetiapine	(Diazepam)	Diazepam Injection		eport #06H-163-0310539-00	(Quetiapine)	Quetiapine	(Phenytoin Sodium)	(Phenytoin Sodium)	(Phenytoin Socium	Phenytoin Injection	Injection	Hydrochloride	Injection	Diphenhydramine Hol	(Diazepam)	(Diazepam)	Diazepam Injection	111111111
	PS	Role		ល	29	Role		វភ ហ	ca ca	SS		ıs Is	į	'n				ŭ		s				SS				Sa			Role
	Zeneca Pharmaceutical					Manufacturer										Manufacturer															Manufacturer
	ORAL	Route	Age:2 YR			Route	Age:35 YR									Route	Age:46 YR														Route
		Dose	Gender:Male		1.5 MG (2 IN 1 D)	Dose	Gender:Female									Dose	Gender:Male														Dose
	1 DAY	Duration	I/FU:I		2	Duration	I/EU:F									Duration	I/FU:I														Datacion

Outcome Death	Date:10/18/06ISR Numbe		Initial or Prolonged Other	Outcome Hospitalization -	Date:10/18/06ISR Number	Outcome Other	Date: 10/17/06ISR Number
PT Affect Lability Aggression Anxiety Drug Interaction Drug Toxicity Hypomania Sommodence	Date:10/18/06ISR Number: 5129649-8Report Type:Expedited (15-DaCompany Report #US-ROCHE-466418		Drug Toxicity Leukopenia	PT Anaemia	Date:10/18/06ISR Number: 5129478-5Report Type:Expedited (15-DaCompany Report #2006UW15289	PT Amnesia	Drug Hypersensitivity Neuroleptic Malignant Report Source Product Syndrome Quetiapine Syndrome (15-Dacompany Report #2006123273
Report Source	rpedited (15-DaCompany Rep			Report Source	pedited (15-DaCompany Rep	Report Source Health Professional	Report Source
Product Klonopin Lithium Prevacid Methadone Seroquel	port #US-ROCHE-466418	Lasix Potassium Chloride Actos Lisinopril Tricor Yalatan Aranesp Nasonex Vitamin B 12 Vitamin B 6 Folic Acid	Ribavirin Interferon Clonazepam Insulin	Product Seroquel	ort #2006UW15289	Product Depon-Evorta Suspension, Sterile (Hedroxyprogesterone Acetate) Klonepin (Clona zepam) Lamictal (Lamotrigine) Seroquel (Quetiapine Fumarate)	Product Queriapine ort #2006123273
I C C PS	,		იიიი	Role PS		Role SS	Role PS
Roche				Manufacturer Zeneca Pharmaceutical		Hanufacturer	Manufacturer
ORAL ORAL DNKHOWN UNKNOWN	Age:41 YR			Route	Age:53 YR	Robute	Route ORAL Àge:
	Gender:Female		0.5-2MG	Dose	Gender:Male	, Dos e	Dose I 50 MG PO Q6PM Gender:Female
	e I/FU:I			DOPPLE	I/FU:F	Duracion	Duration M I/FU:I

Page: 1981

FDA - Adverse Event Reporting System (AERS)

Increased Black Alkalin Black Black Black Black Black Black Brooket Black Black Black Brooket Black Black Brooket Black Black Brooket Black Black Brooket Blooket Brooket Brooket Black Brooket Blooket Black Brooket Blooket Brooket Brooke			Š	Suarmaceu r. r. ear	nn	Chemotherapy Radiation Therapy		Small Intestine Carcinoma	Other
Interested Rough Report Source Product Part Properties Properties Properties Properties Product Properties Product Properties Product Pr	2 YR	6	ORAL		Rolt PS	Product Seroquel	Report Source	PT	Outcome
Interested Blood Altalian Blood Al	Duration	2	,			A Rebort usagaantaasa	dited (15-DaCompany	er: 5132971-2Report Type:Expe	Date:10/23/06ISR Numb
Increased Increased Report Source Product Prod						מפפונים			
Increased Phosphateast Increased Product								Optic Neuritis Visual Field Defect Visual Impairment	Initial or Prolonged
Increased Prospectable Prospec			ORAL		re U	Seroquel	į	Death Death Merabolic Disorder	Outcome Death
Interessed Int	Duration	Dose	Route		Role	Product	Report Source		Date:10/20/0615% WunDe
Filter F		∣N Gender:Femal				Report #2006PK02081	dited (15-DaCompany	v. 5131629-3Report Type:Expe	To the total of the Nimbe
Hondy Alsine Hondy			ORAL	Zeneca Pharmaceutical	to to	Seroquel		Extrapyramidal Disturbance	
Hondratesed Hondratisine Hondratisine Hondratisine Hondratisine Hondratisine Hondratisine Hondratisine Hondratisine Hondratisinisinisinis Hondratisinis Hondratis Hondra	1 YR		ORAL		Sd	Seroquel		Dyskinesia Dyskinesia	Outcome Other
Increased Hoosy Nithine	Duration	Dose	Route		Role	Product	Benort Spurce	II Stateza-twebarr alberrake	Date:10/20/06ISR Numbe
Increased Ellod Alkaline Product Produ	1/FU:1	Gender:Male	-			Report #2006UW19917	wited (15-DaCompany	ייייייייייייייייייייייייייייייייייייי	
Riceased Report Source Product Foundation Role Manufacturer Route Rout					იი	Methadone Unspecified		Consciousness Feeling Abnormal Ill-Defined Disorder	Initial or Prolonged
Increased Hooph Alkaline Phosphalase Increased Hooph Alkaline Phosphalase Increased Hooph Alkaline Hopatic Entraine Hepatic Enzyme Increased Hepat			ORAL		S	Seroquel	Report Source	PT Depressed Level Of	Outcome
Increased Hooph Alkaline Phosphalase Increased Blood Alkaline Phosphalase Increased Blood Biltrubin Increased Gamma-clittubin Increased Formal Command Distribution Increased Hepatic Encreased Whepatic Encreased Formal Depression Froduct Formal Depressed Level Of Consciousness Drug Interaction Malaiss Wydriasis Vision Blurred Formal Consciousness Formal Depressed Level Of Wydriasis Vision Blurred Formal Depression Froduct March 1	Duration	Dose	Route		Role		Tied (Is-Darombany	r: 5131484-lReport Type:Expec	Date:10/20/06ISR Number
Increased Product Pr	I/FU:I	Gender:Male	Age:			Barort #20060W20169			
Increased Blood Alkaline Phosphatise Increased Blood Alkaline Phosphatise Increased Blood Blirmbin Increased Blood Blirmbin Increased Frequel Seroquel PS Zeneca Pharmaceutical Pharmaceutical Increased Hepatic Enzyme Increased Hepatic Enzyme Increased Number: 5131307-DReport Type:Expedited (15-DaCompany Report #2006G801808 Nancy Seroquel PS Zeneca Nanufacturer Route Nanufacturer Route Nanufacturer Route ORAL ORAL ORAL ORAL Dose Dura					н -	Nardil Sertraline		Consciousness Drug Interaction Malaise Hydriasis Vision Blurred	INTERAL OF KEOTOMAGN
Role Manufacturer Routo Dose Duri PS Zaneca ORAL 1 Pharmaceutical ORAL 3 Pharmaceutical Age: Gender:Female			ORAL	Pharmaceutical	2	Seroquei		Delirium	Hospitalization -
Role Manufacturer Routo Dose Duri PS Zaneca 1 Pharmaceutical ORAL 1	Datacron	Dose	Route	Manufacturer	Role	Product	Report Source	P T	
Report Source Product Role Manufacturer Route Dose Durati Seroquel PS Zeneca Pharmaceutical ORAL	?	Gender:Female	Age:			Report #20065801808	ited (15-DaCompany I	:: 5131307-ORepart Type:Exped	Date:10/20/06ISR Number
Report Source Product Role Manufacturer Routo Dose Durati				Lightwarentrebr				Increased Hepatic Enzyme Increased	
Role Manufacturer Route Dose	1 YR		ORAL	Zeneca Zeneca	Sd	Seroquel	Report Source	Blood Bilirubin Increased Gamma-Glutamyltransferase	
	Duration	Dose	Route	Manufacturer	Role			Increased Blood Alkaline Phosphatase Increased	

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FDA - Adverse Event Reporting System (AERS)

Outcome	Date:	Date:11 Outcome Other
ři ři	1/02/061	1/02/D618 e
	SR Number	:R Number
er Confusional St Depressed Leve Consciousness Hyperhidrosis Hypertonia Heuroleptic M Syndrome Pyrexia	: 5142755	: 5142754-5Rep PT Bradycardia Extrasystoles Intentional O Ventricular A
PT Confusional State Confusional State Consciousness Hyperhidrosis Hypertionia Neuroleptic Malignant Syndrome Pyrexta Tromor	-7Report	5142754-Sheport Type: pr Bradycardia Extrasystoles Intentional Overdose Ventricular Arthythmia
gnant e	Date:11/02/06ISR Number: 5142755-7Report Type:Expeditod (15-DaCompany Report #2006Uw20757	Date:11/02/D6ISR Number: 5142754-5Report Type:Expedited (15-Dacompany Report #2006UW20771 Outcome PT Report Source Product Seroquel Excraystoles Intentional Overdose Digoxin
Repo	editod (1	adited (1 Repo
Report Source	5-DaCompa	ad (15-Dacompai Report Source
u	any Repor	iny Report
Product Seroquel EC-Asa Epival Hydrochloro	E #2006UW	t #20060W Product Seroquel Digoxin
Product Seroquel Ec-Aaa Epival Hydrochlorothiazide L-Thyroxine	20757	20771
Role PS C C		Role PS SS
Manufacturer Zeneca Pharmaceutical		Manufacturer Zeneca Pharmaceutical
0 7		0 7
ORAL	Age:80 YR	Age:47 YR Route ORAL
Dose	Gender:Female	Gender:Male Dose
Duration 2 YR]:U3/I	I/FU:I Duration
	•	

Date:11/02/0615R N Dutcome Other	Date:11/02/0615R N Outcome Death
Date:11/02/06ISR Number: 5142757-OReport Type:Expedited (15-DaCompany Report #2006UWZ0742 Outcome PT Rash Other Urticaria Tylenol Arthr	Date:11/92/0615R Number: 5142756-9Report Type:Expedited (15-DaCompany Report #2006UW20967 Outcome PT Report Source Product Seroquel Abnormal Behaviour Lithium Drug Interaction Prevacid Klonopin Methadone
edited (15-baCompany Re Report Source	dited (15-DaCompany Re Report Source
sport #2006UW20742 Product Seroquel Tylenol Arthritis Pain	port #2006UW20967 Product Seroquel Lithium Prevacid Klonopin Methadone
Role FS	Role PS
. Manufacturer Zeneca Pharmaceutical	Manufacturer Zeneca Pharmaceutical
Age: 43 YR Route ORAL	Age:41 YR Route ORAL ORAL
Gender:Male Dose	Gender:Female Dose
I/FU:I Duration 1 MDN	Duration 20 DAY 689 DAY

Date:11/03/06ISR Num		Other	
Date:11/03/061SR Number: 5143037-XReport Type:Expodited (15-DaCompany Report #2006FK020Bl	Orticaria	Rash	D.T.
dited (15-DaCompany Rep			Report Source
ort #2006PK02081	Tylenol Arthritis Pain	Seroquel	Product
	С	es	Role
		Zeneca Pharmaceutical	Role Manufacturer
Age: 262 M		ORAL	Route
2 MON Gender:Female I/FU:F			Dose
e 1/fU:f		1 MON	Duration

	Initial or Prolonged Metabolic Acidosis Nausea Optic Neuritis Vumiting	Death Gastritls Hospitalization - Gastroenteritis		Date:11/03/06ISR Number: 5143037-Xheport Type:Expodited (15-DaCompany Report #2006PK02081
			Report Source	a:Expedited (15-DaCompany
Lgg Lgg	Biocarn Biocarn Blocarn Cotimonazol	Allogurinol	Product	Report #2006PK02081
ററ		G	Role	
		Pharmaceutical	Manufacturer Zeneca	
	INTRAVENOUS INTRAVENOUS	ORAL	Route	.ge:262
			Dose	MON Gender:Female
	₩ 5		00101101	
DAY	×.	Y P	, -	ng.

Freedom Of Information (FOI) Report

Date:11/10/061SR Number: 5147722-5Report Type:Expedited (15-DaCompany Report #2006UW71518 Ontcome	Date:11/10/DEISR Number: 5147721-3Report Type:Expedited (15-DaCompany Report #2006UW15030 Outcome PT Report Source Product ES Zencea Seroquel Pf Pharmaceuti Initial or Prolonged Gait Disturbance Musculoskeletal Stiffness Ceffexor Ceffex	681 Role S S	ype:Expedited (15-DaCompany Report #FAR_1040_2006 Report Source Product Role Literature Diazepam PS Health Hethadone SS Brofessinal Quetapine SS	Date:11/09/06ISR Number: 5151647-9Report Type:Expedited (15-DaCompany Report #DSA_61249_2006 Outcome PT Report Source Product PS Death Cardiac Arrest Literature Diazepam PS Death Drug Abuser Health Methadonc SS Respiratory Arrest Professional Quetiapine SS	
		_	e Manufacturer	e Manufacturer	e Manufacturer
Age: Route GRAL	Age:708 HC Route ORAL ORAL ORAL	Age: Route ORAL	Age:53 YR Route ORAL ORAL ORAL	Age:53 YR Route ORAL ORAL ORAL	Route ORAL ORAL
Gender:Female Dose 12.5 MG AH, 50 MG PM	ON Gender:Female Dose 400 TO 500 MG 60 TO 120 MG	Gender:Male Dose	Gendex: Dose DF PO DF PO	Gender: Dose PO PO PO	100MG QAM PO
Le I/FU:I Duration 6 DAY 6 DAY	e I/FU:F Duration MG 35 MON	I/FU:I Duration	I/FU:I Duration	I/FU:I uration	

Outcome Hospitalization -Initial or Prolonged 24-Aug-2010 10:39 AM

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FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

BEDTIME PO

				Outcome Death Hospitalization - Initial or Prolonged	Date:Il/16/06ISR Num	Outcome Death	Date:il/15/06ISR Numb	Death	Outcome	Date:11/15/06ISR Numb					Outcome Death	Date:11/15/06ISR Numb
			Psychomotor Hyperactivity Sommolence Thirst	PT Bite Compulsions Death Dyskinesia	Date:11/16/06ISR Number: 5152017-XReport Type:Expedited [15-DaCompany Report #US-JNJFCC-2005]102786	PT Cardiac Arrest Completed Suicide Poisoning Respiratory Arrest	Date:11/15/06ISR Number: 5156687—lReport Type:Expedited (15-DaCompany Report #PAR_0975_2006	Completed Suicide Poisoning	PT	Date:11/15/06ISR Number: 5156696-XReport Type:Expedited (15-DaCompany Report #PAR_0976_2006	Tritability Paranoia Sommolence Treatment Noncompliance	Hallucination, Auditory	Anxiety Drug Interaction Drug Toxicity	Aggression Agitation Anger	PT Affect Lability	Date:11/15/06ISR Number: 5156666-4Report Type:Expedited (15-DaCompany Report #T200661275
				Report Source	edited (15-DaCompany R	Report Source Literature Health Professional	dited (15-DaCompany R	Health Professional	Report Source	dited (15-DaCompany Re					Report Source Health	iited (15-DaCompany Re
Seroquel Seroquel	Abilify Abilify	Risperdal	Risperdal Risperdal	Product Risperdal	eport #US-JNJFOC-20051	Product Dowepin Mirtazapine Quetiapine Unknown	eport #PAR_0975_2006	Quetiapine Cocaine Unknown	Product Doxepin	port #PAR_0976_2006		Prevacid (Lansoprazole)	Seroquel Lithium (Lithium)	Klonopin (Clonazepam)	Product Mcthadone	port #T200601275
ភ ស	in to	ស	th th	Role Manufacturer PS	102786	Role Manufacturer PS SS SS		C 88 88	Role Manufacturer PS			C	C SS	ម មា	Role Manufacturer PS	
		ORAL	ORAL ORAL	Route ORAL	Age:	GRAL ORAL ORAL ORAL	Age:44 YR	ORAL.	Route	Age:38 YR				ORAL	Route ORAL .	Age:41 YR
titrated to		0.5 mg AM, mid-day, and 2 mg HS daily	1 mg AM, mid-day, and 2 mg HS daily	initially initially started at 0.5 mg every 4 hours prn, 1 mg daily	Gender:Male	DE PO DE PO DE PO	Gender:	טר 20 סיי	Dr PO	Gender:				1 MG, TID, ORAL	Dose 40 MG, QD, ORAL	Gender:Female
Page: 2028	22 MON	22	IV d	,	I/FU:I		I/FU:I		Duration	I/FU:I					Duration	

Freedom Of Information (FOI) Report

Outcome Hospitalization - Initial or Prolonged	Date:12/13/06ISR Number	Outcome Required Intervention to Prevent Permanent Impairment/Damage	Initial or Prolonged Initial or Prolonged	Outcome	nare.12/13/06ISR Number:	Outcome Hospitalization - Initial or Protonged Required Intervention to Prevent Peramient Impairment/Damage	Date:12/13/06ISR Number:	Required Required Intervention to Prevent Permanent Impairment/Damage	Date:12/13/06ISR Number:	Intervention to Prevent Permanent Impairment/Damage	Outcome PT Required Pa	Date:12/13/06ISR Number:
PT Akathisia	Date:12/13/06ISR Number: 5277456-BReport Type:Periodic	PT Diabetes Mellitus Ill-Defined Disorder Nightmare Rectal Hemorrhage Vision Blurred	nospitalization initial or Prolonged initial or Prolonged initial or Prolonged	PT PT	nara.)2/13/D6TSR Number: 5277453ZReport Type:Periodic	PT Hyponatraemia	5277452-OReport Type:Periodic	envulsion Convulsion	Date:12/13/06ISR Number: 5277451-9Report Type:Periodic		PT Pancreatitis	5277450-7Report Type:Periodic
Report Source Health Professional		Repart S Consumer	Professi	Report 5 Health		Report Source Health Professional		Report Source Health Professional			Report S	
Product Seroquel	Company Report #2004UW10798	Product Seroquel Lithium Xanan Ritali Ritali Clonazepam	onal Methadone Company Report #2006UW06655	Product Seroquel	Company Report #20060W06554	Product Seroquel Trazodone Propranolol	Company Report #Z005UW17066	Product Seroquel	Company Report #2004UW10570	Prozac Clonapin Nexium Synthroid Promethazine Zyprexa	Product Seroquel	Company Report #2006UW06495
Role Manutacturer PS		Role Manufacturer PS C C C	o	Role Manufacturer		Role Manufacturer PS C		Hole Manufacturez PS			Role Manufacturer PS	
ORAL	Age:29 YR	Route	Age:30 YR	Route ORAL	Age:50 YR	Route	Age:46 YR	Route	Nge:		Route ORAL	Age:55 YR
25 MG PO	Gender:Female	Do s e	Gender:Male	Dose 10	Gender:Female	Dose 50 MG RID/200 MG HS	c:Male	Dose	::		Dose Duration 650 MG DAILY PO	Gender:Female
	I/FU:I	Duration	I/FU:I	Duration	I/fU:I	Duracion	1/FU:1	מנמרבטוו	I/FU:I		uration	I/FU:I

24-Aug-2010 10:39 AM

FDA - Adverse Event Reporting System (AERS)

Date:02/13/07ISR Outcome Life-Threatening	Date:02/12/07ISR Outcome Death	Outcome Death	Outcome Date:02/12/07ISR	Date:02/12/07ISR N	Datc:02/12/07ISR Num Outcome Hospitalization - Initial or Prolonged	
Date:02/13/07ISR Number: 5237007-OReport Type:Expedited (15-DaCompany Report #20075E00738 Outcome PT Report Source Product Apitation Apitation Seroquel Loss Of Consciousness Seroquel Suicide Attempt Unresponsive To Stimuli Amoxycylin	Date:02/12/07ISR Number: 5242100-2Report Type:Expedited (15-DaCompany Report #2007-00513 Outcome PT Report Source Product Literature Liberatories Health am) Tablet Methadone (Me Quetiapine (Me Cardio-Respiratory Arrest Professional Among Tablet (Methadone (Me Cardio-Respiratory Arrest Professional Among Tablet	PT Multiple Drug Overdose	Outcome PT Report Source Product Vertigo Quetiapine 25 i Vision Blurred Vision Blurred 25 i Vision Blurred 26 i Vision Blurred 27 i Vision Blurred 28 i Vision Blurred 29 i Vision Blurred 20 i Vision Blurred	Pain Pain Pain Poisoning Restlessness Restlessness	Date:02/12/07ISR Number: 5239595-7Report Type:Expedited (15-DaCompany Report #2007AF000078 Outcome PT Report Source Product Apo-Divalprosx Hospitalization - Constipation (Valproste Dehydration Behydration Hallochation Semisodium)	
dited (15-DaCompany Re Report Source	ited (15-DaCompany Re Report Source Literature Health Professional	Report Source Foreign Health Professional Other	Report Source		lted (15-baCompany Rep Report Source	•
port #20075500738 Product Seroquel Soroquel Amoxycylin Antlemetics	port #2007-00513 Product Diazepam [Watson Laboratories] (Diazep am) Tablet Hethadone (Methadone) Quetiapine (Quetiapin	Product Paracetamol(Paraceta mol) Uhknown Cannabis(Cannabis) Seroquel(Seroquel) Paroxetine	Product Quetiapine 25 Mg port #2006RR-04738	Quetiapine Fumatato (Quetiapine Fumatate) Fumatate) Company Report MCTU 295668	ort #2007AF000078 Product Apo-Divalprosx (Valproste Semisodium)	
Role PS SS	P PS	PS SS	Role PS	in	Role	,
Manufacturer Zeneca Pharmaceutical Zeneca Pharmaceutical	Manufacturer Watson Laboratories	Manufacturer	Manufacturer		Manufacturer	
Age:690 MC Route ORAL ORAL ORAL ORAL ORAL	Age:53 YR Route	Route	Route ORAL Age: 27 YR	Age:27 YR	Age: 30 YR Route ORAL	
MON Gender: Male Dose	Gender:Unknown I/FU:I Dose Duration	Dose 200 MG, BID, ORAL	3 OD PO	Gender: Male	Dose Duration 1000 MG; HS; PO	1
I/FU:1 Duration	n I/FU:I Duration	neston	Duration I/FU:I	1/fu:1	Duration	T/#II:T

Abdominal Pain Arthraigia Back Pain Caesarean Section Dizziness

Date:10/26/07ISR Number: 5499493-OReport Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2007UW02182

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

Report Source

Product Seroquel

Role Manufacturer
PS Zeneca
Pharmaceutical
C
C

ORAL Route

Age:

Gender: Female I/FU: I

Dose

Duration 65 MON

						Hospitalization -	Outcome	Date:10/26/07ISR	Other	Outcome	Date: 10/26/07ISR			Critical	Outcome Death	Date:10/26/07ISR				
				Urethral Stenosis			PT	Date:10/26/07ISR Number: 5499601-1Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2007UW17014	Anorgasma Libido Decreased Sexual Dysfunction	PT	Date:10/26/07ISR Number: 5499588-IReport Type:Expedited (15-DaCompany Report #CA-ASTRAZENECA-2007UW24398			Respiratory Arrest	PT Cardiac Arrest Drug Abuser	Date:10/26/07ISR Number: 5499510-BReport Type:Expedited (15-DaCompany Report #US-ROCHE-526534	Uterine Haemorrhage Vomiting	Tonsillectomy Type 2 Diabetes Mellitus	Skin Laceration Subcutaneous Abscess	Nausea
					D IS		Report Source	Expedited (15-DaCompany		Report Source	Expedited (15-DaCompany)				Report Source	xpedited (15-DaCompany R		(A		
	Seroquel	Seroquel	Seroquel	Seroquel	Seroquel	Seroquel	Product	Report #US-ASTRAZENECA-2	Topamax	Product Seroquel	Report #CA-ASTRAZENECA-2	Unspecified Drugs	Quetiapine	Methadone	Product Diazepam	Report #US-ROCHE-526534				
	ស	SS	ទ	(A	er Er	. 3	Role	071W170	n	Role PS	007UW243!	ស	SS	មា មា	Role PS					
	Zeneca Pharmaceutical	Zeneca Pharmaceutical	Zeneca Pharmaceutical	Zeneca Pharmaceutical	Pharmaceutical	Pharmaceutical		11	Pharmaceutical	Manufacturer Zeneca	98				Manufacturer Roche					
	ORAL	ORAL	ORAL	ORAL	ORAL	ORAL	Route	Age:18007	ORAL ORAL	Route	Age:38 YR	ORAL	ORAL	ORAL	Route ORAL	Age:53 YR				
							Dose	DYGender:Male		Dose	Gender:Female	CHRONIC. EXPOSURE ACUTE ON CHRONIC.	EXPOSURE ACUTE ON	EXPOSURE ACCITE ON	Dose EXPOSURE ACUTE ON	Gender:				
	768 DAY	76B DAY	628 DAY	628 DAY	155 DAY	155 DAY	Duration	1/FU:F		Duration	I/EU:F				Duration	I/fU:I				
ı																				

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FDA - Adverse Event Reporting System (AERS)

Outcome Hospitalization - Initial or Prolonged Other	Date:03/14/06ISR Numbe					Other	Death		Date:03/14/08ISR Numbe					Death	Outcome		Date:03/14/08ISR Number						Initial or Prolonged	Hospitalization -	Outcome		Date:03/14/08ISR Number	Life-Threatening	Cut come	Date:03/14/DBISR Number
PT Cerebrovascular Accident Headache Pain	Date:03/14/06ISR Number: 56/036/=5keport Type:wirect		Sepsis Vomiting	Pheumonicis Chemical	Dyspacea	Aspiration Bronchial	Abdominal Distension	PT	Date:03/14/00ISR Number: 5664782-3Heport Type:Expedited (15-DaCompany Report #BR-ASTRAZENECA-2008UW04991		Road Tratfic Accident	Disorder	Obstructive Airways	Accidental roisoning Headache	THE PROPERTY OF THE PARTY OF TH		Date:03/14/08ISR Number: 5664734-3Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2008UW05031						Pulmonary Embolism	Pneumonia	Congestive Cardiomyopathy	ŀ	Date:03/14/08ISR Number: 5664618-DReport Type:Expedited (15-DaCompany Report ∦NZ-ASTNAZENECA-2008AC00638	Loss Of Consciousness Overdose	Tri Tri	Date:03/14/08ISR Number: 5664517-9Report Type:Expedited (15-DaCompany Report #JE-ASTRAZENECA-2008AF01843
Report Source								Report Source	dited (15-DaCompany Re							Report Source	ited (15-DaCompany Re									Benort Source	ited (15-DaCompany Rep		Report Source	lted (15-DaCompany Rep
Product Seroquel 50mg John Hopskins	1	Company Report #CTU 328787		Topamax	Leurogen	Tentetol	Seroquel	Product	port #BR-ASTRAZENECλ-20	Methadone	Topamax	Valium	Xanax Xanax		Seroquel	Product	oort #US-ASTRAZENECA-200	Benztropine	DCC.	Renytropine	Citalopram	Citalopram	Quetlabine		Quetiapine	Product	ort #NZ-ASTRAZENECA-200	Seroquei	Product	ort #JP-ASTRAZENECA-200
b2 RoTe	,			G	G	n	re tr	Role	08UW049	n	a	, Ct	u f	â	Sd	Role	08080500		ינ	ი	n	n	ć	o a	Sã	Role)BAC0063	3	Role	8AP0184
John Hopskins							Zeneca Pharmaceutical	Manufacturer	91					Pharmaceutical	Zeneca	Manufacturer	11						Pharmaceutical	Zanoca	Zeneca	Manufacturer	65	Pharmaceutical	Manufacturer	Б
ORAL	Route	Age: 42 YR		ORAL	ORAL	ORAL	ORAL	Route	Age:11 YR					ORAL	!	Route	Age:36 YR									Route	Age:20 YR	ORAL	Route	Age:44 YR
1 TABLET 1 TIMES A DAY	Dose	Gender:Female						Dose	Gender:Male							Dose	Gender:Female									Dose	Gender:Female		Dose	Gender:Female
	Duration	le I/FU:I						Duration	I/FU:I							Duration										Duration			Duration	1/FU:I

FDA - Adverse Event Reporting System (AERS)

				იი	Zuclopenthixol			
		ORAL	Zeneca Pharmaceutical	SS	Seroquel	creased	Weight Increased	
		ORAL	Zeneca Pharmaceutical	ps	Seroquel			Other
Duration	Dase	Route	Manufacturer	Role	Product	Report Source	8	
emale I/FU:F	Gender:Female	Åge:	99	007AP0439	port #AU-ASTRAZENECA-2	Date:03/20/08ISR Number: 5674765-0Report Type:Expedited (15-DaCompany Report #AU-ASTRAZENECA-2007AP04389	/20/08ISR Number: 5674785-0	Date: 0
	HINDRIA		Janssen-Cilag	S.	Торатах			
	unknown		Unknown	SS	Seroquel			
	unknown		Unknown	SS	Diazepam			
	unknown		Upjohn Company, The	SS	Xanax		Cedena	
	unknown		Unknown	S	Methadone	Loss Of Consciousness	Loss Of Co	
		ORAL	Pharmaceuticals Inc.	t	Effexor Ar		Fall	
		ORAL	Pharmaceuticals Inc.	n n		eity	Asphyxia Drug Toxicity	Death
Duration	Dose	Route	Manufacturer Wyeth	Role	Product	Report Source	PT	Outcome
	Gender:Female	Age:			port #US-WYE-H03044608	Date:03/20/08ISR Number: 5674043-4Report Type:Expedited (15-DaCompany Report #US-WYE-HD3044608	/20/08ISR Number: 5674043-4	Date: 03
				SS	Risperdal			
		ORAL	Zeneca Pharmaceutical	SS	Seroquel			
		ORAL	Pharmaceutical				Death	Death
Saracto:	tou	Route	Manufacturer Zeneca	Role PS	Product	Report Source	P.T.	Outcome
				OBENODES.	port #DE-ASIKAZENECA-Zu	Date:03/19/08ISR Number: 5673277-2Rcport Type:Expedited (15-DaCompany Report #DE-ASIKAZEMECA-ZUGERNUGEN	/19/08ISR Number: 5673277-2	Date:03
male I/FU:I	Gender:Female	Age:86 YR		000000000000				
				SS	Temesta Alprazolam	Blood Luteinising Hormone Increased	Blood lute Increased	
				2 55	Cisordinol		Increased	
		ORAL	ccutical	: ;	500	icle	Blood Follicle Stimulating Hormone	Other
Duration	Dose	Route	Manufacturer Zeneca	Role	Product	Report Source	Id	Outcome
	DY Gendor:Female	Age:9230 D		08AC00694	oort #NL-ASTRAZENECA-20	Date:03/19/08ISR Number: 5673113-4Report Type:Expedited (15-DaCompany Report MNL-ASTRAZENECA-2008ACD0684	19/08ISR Number: 5673113-41	Date: 03
10		ORAL		C	Risperdal			
;	200-800MG	ORAL	Zeneca Pharmaceutical	25	Seroquel			
u1	200-800MG	ORAL	Pharmaceutical		Seroguel			
		ORAL	ceutical					
		ORAL	Pharmaceutical Zeneca	S.	Seroquel			

	Initial or Protongeo	Outcome Hospitalization -	Date:05/08/08ISR Number						Congenital Anomaly Other	Outcome	Date:05/08/08ISR Number		Hospitalization - Initial or Prolonged	Outcome	Date:05/08/08ISR Number				Other		nara.05/08/OBISR Number:
	Multiple Drug Overdose Accidental	Pysarthria Dysarthria	Date:05/08/08ISR Number: 5736824-8Report Type:Expedited (15-Dacompany Report #DSA_30923_2007	Tricuspid Valve Incompetence Wolff-Parkinson-White Syndrome	Respiratory Depression Supraventricular	Dysfunction Mitral Valve Incompetence	Neonatal Left Ventricular	brug Withdrawal Syndrome	Drug Exposure During	PT	Date:05/08/08ISR Number: 5732143-4Report Type:Expedited (15-DaCompany Report #US-ABBOTT-08P-163-0437462-00	Lethargy Syncope	Abnormat benevious Blood Pressure Decreased	PT	Date:05/08/08ISK Number: 5732011-8Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2008UW09023				Blood Prolactin Increased Breast Discharge	ָּיָב.	nara:n3/08/08ISR Number: 5731912-4Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2008UW08919
	Professional Other	Report Source Foreign Health	dited (15-DaCompany Re							Report Source	iited (15-DaCompany Rep			Report Source	lited (15-DaCompany Rep					Report Source	ited (15-DaCompany Rep
Tricyclic Antidepressants Lsd Methadone Amphetamine Salts	Scroquel (Quetiapine)	Product Tavor (Lorazepam)	port #DSA_30923_2007		Zidovudine	Quetiapine Methadone	Hydroxyzine	Atazanavir Sulfate		Product Norvir Soft Gelatin	oort #US-ABBOTT-08P-163-		Inderal	Product Seroquel	ort #US-ASTRAZENECA-200	Indroto ineraby	Statin Therapy	Clonezepam Cymbalta	Seroquel	Product	ort #US-ASTRAZENECA-200
ខ្លួន	SS	Role PS			r	8 8	i in i	n Ca	S CO	Role	-043746		SS	Role	CO 6 OMOB	r	0.00	000	, n	Role	80W0891
		Manufacturer								Manufacturer	2-00		Pharmaceutical	Manufacturer Zeneca					Pharmaceutical	Manufacturer	
ORAL	ORAL	Route ORAL	Age:			TRANSPLACENTAL	TRANSPLACENTAL	TRANSPLACENTAL	TRANSPLACENTAL	Route	Age:		ORAL	Route	Age:28 YR			ORAL	ORAL	Route	Age:44 YR
(DF ORAL)	(3 DF QD ORAL)	Dose (1 MG QD ORAL)	Gender:Female							Dose	Gender:Male			Dose	r:Female					Dase	Gender:Female
		Duration								Duration	I/FU:F			Duration	I/FO:I					Duration	1/fU:1

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

				ss	Methadone		Overdose	
		ORAL	Zeneca	Ş	Seroquel		Arrhythmia	Death
Duration	Dose	Route	Manufacturer	Role	Product	Report Source	7	
1/FU:1	Gender:	Age:	168	,-2008UW1133	Report #US-ASTRAZENECA	dited (15-DaCompany	Date:06/06/08ISR Number: 5761280-3Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2008UWII338	Date:06/06/08ISR
Duration 519 DAY	Dose	Route ORAL	Manufacturer Zeneca Pharmaceutical	Role PS	Product Seroquel	Report Source	PT Death Type 2 Diabetes Mellitus	Outcome Death
	93 DYGender:Female	Age:14793 I	á	-2007WW1097	Report #US-ASTRAZENECA	dited (15-DaCompany	Date:06/06/08ISR Number: 5761250-SReport Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2007UW10974	Date:06/06/08ISR
Duration	Doxe	Route	Manufacturer Zenoca Pharmaceutical	Role PS	Product Seroquel Dafalgan Codeine	Report Source	PT Paralysis	Outcome Other
I/FU:I	Gender:Male	Age:34 YR	7	-2008AC0142	leport #BE-ASTRAZENECA-	dited (15-DaCompany E	Date:06/06/08ISR Number: 5761249-9Report Type:Expedited (15-DaCompany Report #BE-ASTRAZENECA-2008AC01427	Date:06/06/08ISR
Duration 2 YR 2 MON 2 YR	Dase	ROUTE ORAL ORAL ORAL	Manufacturer Zeneca Pharmaceutical	Role Ps Ss Ss	Product Seroquel Epilexter Prozac Benexol Legalon Leguktroid Rivotril	Report Source	ET Hypernatraemia	Date:Ue/Ve/Velen Outcome Other
I/FU:I	Gender: Female	Age:44 YR		-2008AC01414	epoit #ES-ASTRAZENECA-	dited (15-DaCompany R	nor/oc/ogree Number: 57K1044-NBenort Type:Expedited (15-DaCompany Report #ES-ASTRAZENECA-2008AC01414	7
Duration	Dose	Route ORAL ORAL	Manufacturer Zeneca Pharmaceutical	Role PS SS	Product Seroquel Prolong Haloperidol	Report Source	pT _ Leukopenia nged	Outcome Hospitalization - Initial or Prolonged
1/FU:1	Gender:Male	Age:		·2008PK01186	eport #DE-ASTRAZENECA-	ilted (15-DaCompany R	Date:06/06/03ISR Number: 5761010-5Report Type:Expedited (15-DaCompany Report #DE-ASTRAZENECA-2008FK01186	Date:06/06/08ISR
Duration		Route	Zeneca Zeneca Pharmaceurical	C PS	eport HUS-ASIRALEMENA Product Seroquel Paxil	Report Source	Date:06/06/08ISR Number: 5760867-lReport Type:Expedited (13-DaCompany Report Mus-AsirkAuricum Role: Outcome PT Report Source Product Role: Abdominal Pain Upper Report Source Seroquel PS Abdominal Disorder Ps Disturbance In Attention Irritability Suicidal Ideation Tremor Tremor Trichotillomania	Date:06/06/08ISR Outcome Other
I/FU:I	Gender:Female	Ace: 13 YR		າດດຂາເພາ 1 <u>ດ</u> ງ 6			· ·	

Outcome Death	Date:07/31/08ISR Numb	Hospitalization - Initial or Prolonged	Date:07/31/08ISR Numb		Outcome Other	Date:07/31/08ISR Numb	Outcome Other	Date:07/31/08ISR Numbe	Outcome Hospitalization - Initial or Prolonged Other	Date:07/31/08ISR Numbe	
PT Electrocardiogram Ot Prolonged	Date:07/31/08ISR Number: 5828816-5Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2008UW11338	Blood Pressure Decreased Dysphagia Fall Sommolence	Date:07/31/08ISR Number: 5828713-5Report Type:Expedited (15-DaCompany Report #G5-ASTRAZENECA-ZUUHGHU1143 Report Source Product Role Role		PT Gait Disturbance Oculogyric Crisis	Date:07/31/08ISR Number: 5828571-9Report Type:Expedited (15-DaCompany Report #AU-ASTRAZENECA-2007AP05925	PT Blood Creatine Phosphokinase Increased Electrocardiogram Abnormal Neutrophil Count Increased Tachycardia White Blood Cell Count Increased	Date:07/31/08ISR Number: 5828516-lReport Type:Expedited (15-DaCompany Report #AU-ASTRAZENECA-2008AP057Z0	PT Blood Sodium Decreased Inappropriate Antidiuretic Hozmone Secretion Water Intoxication	Date:07/31/081SR Number: 5828501-XReport Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2808UW11400	Infrequent Bowel Movements Oliguria Pancreatic Cyst Pancreatis Chronic Thrombosis Vomiting
	edited (15-DaCompany R	•	edited (15-DaCompany R		Report Source	dited (15-DaCompany R	Report Source	dited (15-DaCompany Re	Report Source	dited (15-DaCompany Re	Report Source
	eport #US-ASTRAZENECA-	Seroquel Lithium Depakote Diazepam Zopiclone	eport #GB-ASTRAZENECA-; Product		Product Seroquel Luvox	eport #AU-ASTRAZENECA-2	Product Quetiapine Fumarate Pimozide Amisulpride	eport #AU-ASTRAZENECA-2	Product Seroquel Depakote	port #US-ASTRAZENECA-2	Product Seroquel Seroquel Idthium Wallbutrin
	2008UW11338	C C C C C C C C C C C C C C C C C C C	2008GB01145 Role Manufacturer		Role Manufacturer P5 Uns C	2007AP05925	e PS SS SS	008AP05720	Role Manufacturer PS Uns C	008UW11400	Role Manufacturer PS Uns SS Uns C
	Åge:	ORAL ORAL ORAL ORAL ORAL	Route	Ace - 215H1	Route ORAL ORAL	Age:11326	Route ORAL	Age:27 YR	Route	Age:	Route ORAL ORAL
	Gender:		Dose	Ame:21581 DYGender:Male	Dose 25-50 MG LONG TERM USER	Age:11326 DYGender:Female	Dose	Gender:Male	Dos e	Gender:Female	Dose
Page: 4073	I/FU:F	26 DAY	Duration	1/EU:I	Duration		Duration	1/FU:1	Duration	e I/FU:F	Dutation 36 MON 36 MON 62 MON 62 MON

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

Outcome Death	Date:09/18/08ISR Numbe	Date:09/18/08ISR Numbe Outcome Other		Outcome beath	Date:09/18/08ISR Numbe	Date:09/18/0815K Number Outcome Other		Outcome Othor	Data . 00/18/08TSB Nimber	
PT Death	r: 5898270-4Report Type:	r: 5888249-2Report Type: PT Drug Interaction Hypotension	à	PT Completed Suicide Overdose	r: 5888198-XReport Type:	ET PT Agranulocytosis		PT Cardiac Arrest	: 5888176-4Report Type:E	Visual Acuity Reduced Weight Decreased Weight Increased
Report Source	nara:09/18/09ISR Number: 588827D-4Report Type:Expedited (15-DaCompany Report #CH-ASTRAZENECA-2008FK02044	Date:09/18/08ISR Number: 5888249-2Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2008UW18988 COUTCOME PT Report Source Product PS Other Drug Interaction C Other Hypotension Yethadone I		Report Source	Date:09/18/08ISR Number: 5888198-XReport Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2008UW19248	Report Source	Type-Fyredited (15-DaCompany Report #US-ASTRAZENECA-2008UW19092	Report Source	n-ro-ng/1g/ngTsR Number: 5888178-4Report Type:Expedited (15-DaCompany Report #JF-ASTRAZENECA-2008AP07251	Report Source
product Seroquel Seroquel Seroquel Seroquel Seroquel Seroquel Seroquel Fluanxol Fluanxol Fluanxol Fluanxol Fluanxol	Report #CH-ASTRAZENECA-2	eport #US-ASTRAZENECA-2 Product Seroquel Lopressor Methadone		Product Seroquel Acetaminophen Benrodiazepine Gabapentin Primidone	eport #US-ASTRAZENECA-20	Product Seroquel Depakote	eport #US-ASTRAZENECA-20	Product Seroquel	port #JP-ASTRAZENECA-20	Product Seroquel Seroquel
Role Manufacturer PS SS	008PK02044	GOBUW18996 Role Manufacturer PS C		Role Manufacturer PS SS SS SS)08UW1924B	Role Manufacturer PS C)08UW19092	Role Manufacturer PS	08AP07251	Role Manufacturer PS SS
Route ORAL ORAL ORAL ORAL ORAL ORAL ORAL ORAL	Age:47 YR	Route ORAL	A	ROULE ORAL ORAL ORAL ORAL ORAL	Age: 68 YR	ROUTE ORAL	Age: 25 YR	Route ORAL	Age:	Route ORAL ORAL
Do so n	Gender:Female	Dose	Gender: Male	C O M	Gender:Female	Dose	Gender:Male	Dose SEROQUEL PRESCRIBED FOR PATIENT'S SON/DAUGHTER	Gender: Female	Dose
Duration 98 100 98 100 10 00X 10 00X 8 00X 10 00X 10 00X 11 00X	e I/FU:I	Duration	I/FU:I	200		Duration	I/EU:I	Duration S 1 DAY	I/FU:I	Duration 2 YR

FDA - Adverse Event Reporting System (AERS)

Date:11/06/DBISR Number: 5943779-XReport Type:Expedited (15-DaCompany Report #FT-ASTRAZENBCA-2008SED5066 Outcome PT Report Source Product Role Decreased White Blood Cell Count Decreased Decreased	Date:11/06/08ISR Number: 59436B3-7Report Type:Expedited (15-DaCompany Report #U5-JNJFOC-20070100240 Outcome PT Report Source Product Risperdal Photophobia Seroquel S	Outcome PT Report Source PT Rightalization - Agitation Agitation Akathisia Akathisia Rightaliar Prolonged Akathisia Rightaliar Prolonged Akathisia Rightaliar Report Source Rightaliar Rightaliar Report Source Rightaliar Report	Hental Disorder Hental Disorder 106/0815R Number: 5943682-5Report Type:Expedited (15-DaCompany Report	Type:Expedited (15-DaCompany Report Report Source	Date:11/06/0815R Number: 5943618-7Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2008AC02861 Outcome PT Report Source Product PS Death Drug Toxicity PS Report Source Outcomethorphan SS Death Rultiple Drug Overdoxe SS Dextromethazine SS
ype:Expedited (15-DaCompany Roport #FI-ASTRA Report Source Product Seroquel	ype:Expeditud (15-DaCompany Report #US-JNJFO Report Source Product Rispertal Seroquel	Report Source Product Risperdal Scroquel Olanzapine Risperdal Zoloft Clonidine	pe:Expedited (15-DaCompany Report #US-JNJFOC-2	pe:Expedited (15-DaCompany Report #US-PFTZER Report Source Product	pe:Expedited (15-DaCompany Report #US-ASTRAZENECA Product Queriapine Methadone Daxitomethotphan Promethazine
AZENECA-2008SE05066 Role Manufacturer PS	oc-20070100240 Role Manufacturer PS SS	Role Manufacturer 88 88 85 85 85 85 85 85 85	35 55 55 55 55 55 6 C C C C C C C C	R INC-2007051662 Role Manufacturer PS	ZENECA-2008ACO2861 Role Manufacturer ES ES S 5 Orphan SS
Age:4D YR Route CRAL	Age: Route	Route	ge:	Age:44 YR Route	Age:48 YR Route
R Gender:Female Dose	Gender:Male Dose	Dose	Gender: Male	Gender:Female Dose	Gender:Female Dose
le I/fU:I Duration	1/fU:1 Duration	Duration	I/FU:1	1/EU:E	. I/EU:I Duration

Outcome Hospitalization - Initial or Prolonged	Date:11/07/08ISR Numb		Outcome Other	Date:11/07/08ISR Numb		Other	Outcome	Date:11/07/08ISR Number:	Outcome Death	nate:11/07/08ISR Numbe	Outcome Other	Date:11/07/08ISR Numbe
PT Condition Aggravated Drug Interaction Gamma-Glutamyltransferase Increased	Date:11/07/08ISR Number: 5947660-lReport Type:Expedited (15-DaCompany Report #1000001575	Inappropriate Schedule Of Drug Administration Muscle Rigidity Restless Legs Syndrome Tremor	PT Hypotonia	Date:11/07/DBISR Number: 5945919-lReport Type:Direct		to yellab take o yelevone	PH CONTRACTOR	sr: 5945656-7Report Type:Expedited (15-DaCompany Report #US-PFIZER INC-2008093395	PT Drug Toxicity Multiple Drug Overdose	naro.:11/07/0815K Number: 5945315-OReport Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2008ACO2861	PT Accidental Overdose Intentional Drug Misuse Malaise Mrong Drug Administered	Date:11/07/08ISR Number: 5945072-BReport Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2008UWZ4661
	adited (15-DaCompany Re		Report Source				Report Source	dited (15-DaCompany Rep	Report Source	ited (15-DaCompany Rep	Report Source	ited (15-DaCompany Repo
	port #1000001575	Seroquel 50 Mg	Product Seroquel 200mg	Company Report #CTU 355414	Lipitor Lisinopril All Other Therapoutic Products Abilify	Seroquel Effexor Citalopram Clonazepam Reyataz All Other Therapeutic Products Epivir Acetylsalicylic Acid	Product Chantix Tablets	ort #US-PFTZER INC-200	Product Quetiapine Methadone Dextromethorphan Promethazine Diazepam	ort #US-ASTRAZENECA-20	Product Seroquel	ort #US-ASTRAZENECA-200
		ta Vi	Role Manufacturer PS				Role Manufacturer PS	8093395	Role Manufacturer ps ss ss ss ss	08AC02861	Role Manufacturer PS)8UW24661
	Age:42 YR	ORAL	Route ORAL	Age:83 YR			Route	Age:	Route GRAL GRAL ORAL GRAL GRAL	Age:48 YR	Route ORAL	Age:17 YR
	Gender:Male	150 MG TWICE DAILY PO	200MG EVERY 8 HOURS PO	G			Dose	Gender:Male	Dose	Gender:Female	Dose POSSIBLE SEROQUEL OVERDOSE	Gender:
Page: 44	1/FU:1	ři	buracton	I/FU:I			Duration	1/FU:1	Duration	1/FU:F	Duration	I/EU:I

Outcome Death	Date:01/08/09ISR	Date: 01/08/09135 NUMBER. Outcome Death	7 - t	Date:01/08/09ISR Outcome Death		Outcome Death	Date:01/08/09ISR	Outcome Death	Date:01/08/09ISR N	
PT Aspiration Brain Oedema Brain Oedema Multiple Drug Overdose Accidental Self-Medication	Date:01/08/09ISR Number: 6034663-4Report Type:Expedited (15-DaCompany Report #PAR_02487_2008	PT Completed Suicide Intentional Drug Misuse	Number: 60345E0-4Report Type:Expedited (15-DaCompany Report #8040901	Date:01/08/0915R Number: 6034530-6Report Type:Expedices (12-Datumpeny Neptron Product Outcome PT Completed Suicide Literature Quetiapi Beath Intentional Drug Misuse Health Benzodia Professional Derivati Other Haprotil Haprotil Tramadol		PT Completed Suicide Intentional Drug Misuse	Date:01/08/09ISR Number: 6034231-4Report Type:Expedited (15-DaCompany Report #80402799	PT Completed Suicide Intentional Drug Misuse	Date:01/08/09ISR Number: 6034217-XReport Type:Expedited (15-DaCompany Report #8040757	
	edited (15-DaCompany R	Report Source Literature Health Professional	dited (15-DaCompany R	Report Source Literature Health Professional Other	dired (15-DeCompany Re	Report Source Literature Health Professional	dited (15-DaCompany Re	Report Source Literature Health Professional	ited (15-DaCompany Rep	
	epoit #PAR_02487_2008	Product Acetaminophen-Hydrocodome Marijuana Lithium Sertraline Quetlapine Diphenhydramine Methadone Clonazepam	eport #8040901	Product Product Methocathamol Quetiapine Benzodiazepine Derivatives Haprotiline Hydrocodone Tramadol	sport #000053	Product Hydrocodone Bitartrate And Acetaminophen Carisoprodol Quetiapine Zolpidem	port #80402799	Product Hydrocodone/Acetamin ophen Quetiapine Clonazepam Sertraline Pregabalin Carisoprodol	port #8040757	
		Role Manufactuzer P5 SS		Role Manufacturer PS SS SS SS C C		Role Manufacturer PS SS SS SS		S S S S S S S S S S S S S S S S S S S		
	Age:12 YR	Route	Age:32 YR	Route	Age:50 YR	200 116	Age:58 YR		Age: Ja In	מע פר
	Gender:Female	Doge	Gender:Male	Dose	Gender:Female	Dose	Gender:Female	;	Doxe	Gender: Female
Page: 4587	e I/FU:I	Duration	I/fU:I	Duration	I/FU:I	Duration	I/FU:I		Dur	I/FU:I

Date:01/16/09ISR Number: 6039901-XReport Type:Expedited (15-DaCompany Report #US-ABBULT-USE-103-0000000000000000000000000000000000		Date:01/16/09ISR Number: 6039857-XReport Type:Expedited (15-DaCompany Report #US-ABBOTT-09P-163-0497813-00 Outcome PT Report Source Product PS Death Cardio-Respiratory Arrest Bupropion SS Outlaspine SS Baclofen SS Baclofen SS	Date:01/16/09ISR Number: 6039853-2Report Type:Expedited (15-DaCompany Report #US-ABBOTT-092-163-0497712-00 Outcome FT Report Source Product Role Malproic Acid PS Death Cardio-Respiratory Arrest Quetiapine S3	Date:01/16/09TSR Numbor: 6039794-OReport Type:Expedited (15-DaCompany Report #US-ABBOTT-09P-163-0497881-00 Outcome PT Report Source Product Role Ma Death Cardio-Respiratory Arrest Valproic Acid PS	
pedited (15-DaCompany Report Source		sedited (15-DaCompany Re) Report Source	edited (15-DaCompany Rep Report Source	edited (15-DaCompany Rep Report Source	
eport #US-ABBULT-USE-1 Eroduct Levethyroxine Quetiapine Mirtazapine Trazodone Trazodone Gabapentin Topizamate Hydroxyzine Ezetimibe	Prometria zane Methadone Du Loxetine Clona zepam Zolpidem Lithium Limotrigine Efsylzenz Emtricitabine W/Tenofoviz	port #US-ABBOTT-09P-16 Product Levothyroxine Bupropion Quetiapine Barlofen	port #US-ABBOTT-09F-16: Product Valproic Acid Quetiapine	oort HUS-ABBOTT-09P-163 Product Valproic Acid Quetiapine	Flexeril Lamictal Cogentin Lexapro Albuterol
Role Manufacturer PS PS SS		J-0497813-00 Role Manufacturor PS SS SS SS	-0497712-00 Role Manufacturer PS S5	-0497881-00 Role Manufacturer PS SS	C C S S S S S S S S S S S S S S S S S S
	Age: 47 YR	Age:37 YR	Age:48 YR Route	Age:20 YR Route	UNKNOWN
		Gender: Male Dose Ingestion Ingestion Ingestion Ingestion Ingestion Ingestion	Gender:Male Dose Route Route ingestion Route Ingestion	Gender:Male Dose Ingestion + unknown Ingestion + unknown	
Duration	. 1/EO:I	I/fU:I Duration	I/EU:I Duration	I/FU:I Duration	

Ercedom Of Information (FOI) Repo

Page: 46					Report Source Literature Health	PT Completed Suicide	Outcome Death
1/fU:I	Gender:Fomale	Age:47 YR		009-190002-NL	6067868-7Report Type:Expedited (15-DaCompany Report #2009-190002-NL	ber: 6067868~7Report Type:Exped	Date:02/03/09ISR Number:
				ne on acepine inc inc na na	Literature Rowandi Health Methadol Professional Greaine Benzedii Quetiap Cyclobe Marijua	Appiration Body Temperature Increased Suicide Completed Suicide Convulsion Delixium Delixium Drug Toxicity Electromechanical Dissociation Flushing Foreign Body Heart Rate Increased Hyperhonia Hypertonia	Death Death
Duration	Dose D	Route	Role Manufacturer		Boost Course Product	Date:02/03/09TSR Number: bUbb//-/Keport ifteria/poeters tourns Product	Date:02/03/09TSR Numbe
I/FU:I	Gender:Female	Age:23 YR		0600001560	red (15-DaCompany Report #20		
				Vitamin B12 (Cyanocobalamin) C	Vitam (Cyan		
				CL	Vera		
				Provigil (Modafinil) C	Provi		
				Neurontin (Gapapentin) C	Neuro		
				Multivitamins) C	Multi		
				Therapeutic	There		
				Sustained Release C Multivitamin	Susta		
				nate	Lithi		
				Lamictal (Lamotricine) C	Lamictal /iamotri		
				Extended Release) C	Exten		
				Effexor Sr	Effex		
				Cymbalta (Duloxetine) C	Cymbalta (Duloxet		
	200MG TABLET 200 MG QHS DRAL			(Quetiapine) PS		Atrioventricular Block First Degree	Hospitalization - Initial or Prolonged Other
puration	Dose	Route	e Manufacturer	ct Role	Report Source Product	PT	
I/fU:L	Male	Age: G		364894	Company Report #CTU 364894	Date:02/03/09ISR Number: 6064410-lReport Type:Dire t	Date:02/03/09ISR Number
				Freedom Of Information (FOI) Report	Freedom Of Info		

Page: 4672

Laboratories) Quetiapine	Freedom Of Information (FOI) Report
SS Watson Laboratories SS	port
UNK	

24-4-2010		Death		Date: 02/04/09:																		Death	Outcome	Date: 02/01/07:	Date: 02/04/09I													Outcome		Data:02/04/09IS
10:39 AM		Cardio-Respiratory Arrest	만기	nare:02/04/09ISR Number: 6065477-7Report Type:Expedited (15-DaCompany Report #US-WATSON-2009-00683																		Eco Cit	P I		nate - 02/04/09ISR Number: 6065408-XReport Type:Expedited													PT Cardio-Respiratory Arrest		nate 02/04/09ISR Number: 6065399-IReport Type:Expedited (15-DaCompany Report #US-WATSON-2009-00574
			Report Source	dited (15-DaCompany R																			Report Source		ited (15-DaCompany Re													raport company	Banott South	ted (15-DaCompany Rep
	(watson Laboratories)	Buspirone Hydrochloride	Product	eport #US-WATSON-2009-00	Ethanol	Thyroid Preparations	Fexofenadine	Quetiapine	W/Optoid	Acetaminophen	Laboratories)	(Watson	Trazodone	Laboratories)	Carisoprodol (Watson	Laboratories)	(Watson	Tramadol	Laboratories)	Clonarenam (Watson	(Watson	Extended Release	Naproxen Sodium	8101	(15-DaCompany Report #US-WATSON-2009-30573	Ethanol	Quetiapine	Methadone	Laboratories)	Hydrochloride	Cyclobenzaprine	Laboratories)	(Watson	Hydrochloride	Hydroxyzine	(Watson	Hydrochloride	Buspirone	Product	port #US-WATSON-2009-005
	PS		Role	683			S I	in t	ກປ	3	SS			S		SS			SS		Sa			Role	73	SS	SS	22	S			S			1	Sa			Role	7.4
	Watson Laboratories		B Manufacturer								Watson Laboratories			Watson Laboratories		Watson Laboratories			Watson Laboratories		Watson Laboratories			Manufacturer					Watson Laboratories			Watson Laboratories				Watson Laboratories			Manufacturer	
			Route	Age:51 YR																				Route	Age:39 YR														Route	Age:39 YR
	unknown		Dose	Gender:Female							CNR			2	TINK	UNK			ONK		unknown			Dase	Gender:Female				UNK				INK			unknown			Dose	Gender:Female
Page: 4676			Duration	e I/FU:I																				Duration	I/EU:I														Duration	1/50:1

Freedom Of Information (FOI) Report

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								אל פניתו תוחקים אל	
Page: 46								Outcome Hospitalization – Initial or Prolonged	HEO
I/FU:I	Gender:Male	Age:		1001	6066852-7Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20060402001	edited (15-DaCompany	:: 6066852—7Report Туре:Ехр	Date:02/05/09ISR Number:	g
Duration 40 MON 40 MON	Dose	Route ORAL ORAL	Manufacturer	Role PS SS	Product Seroquel Seroquel	Report Source	PT Senile Dementia	Dutcome Death	p 0
I/EU:F	Gender:Male	Age:	5 1	BUW2536	Report #US-ASTRAZENECA-200	dited (15-DaCompany F	n.r07/NG/NGTKR Number: 6066848-5Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2008UW25366	sts.02/05/05TSB Nimber	7
				ស ល ល ល ល ស ល ល ល	Lithium Levothyroxine Lewothyroxine Lemotrigine Efaviren Emtricitabine W/Tenofovir				
	UNK		Watson Laboratories	88 88 88 88					
	UNK		Watson Laboratories Watson Laboratories	ន ន	(Watson Laboratories) Bupropion Hydrochloride X1 (Watson Laboratories) Promethazine (Matson				
	UNK		Watson Laboratories	S TE	Laboratories) Clonazepam (Watson Laboratories) Zolpidem Tartrate		Cardio-Respiratory Arrest		De
Duration	Gender:Male Dose	Age:37 YR Route	Manufacturer	Role	eport #U5-WATSON-2009-0066 Product Product	dited (15-DaCompany Re Report Source	Date:02/05/09ISR Number: 6066803-5Report Type:Expedited (15-DaCompany Report #U5-WATSON-2009-00663 Outcome PT Report Source Product	Date:02/05/09ISR Number: Outcome	Out Dat
				66 6666	Olarzapine Diazepam Biperiden Haldel Haldel Valproate Sodium + Valproate Acid Lithium		Dyphagia Hypokinesia Muscle Rigidity Salivary Hypersecretion Somnolence Speech Di order	(a. (a. 7. T.	
Duration 3 DAY 18 DAY	Dose	Route ORAL	Manufacturer	Role +	Product Seroquel Sr Olanzapine	Report Source	PT Coordination Abnormal Diplopia	Outcome E	Outco
I/FU:I	Gender:Male	Age:		AC00463	port #PT-ASTRAZENECA-2009	ited (15-DaCompany Re	Date:02/05/09ISR Number: 6066774-IReport Type:Expedited (15-DaCompany Report #FT-ASTRAZENECA-2009AC00463	n2/05/09ISR Number:	7

24-Aug-2010 10:39 AM

FDA - Adverse Event Reporting System (AERS)

			Outcome Death	Data:02/05/09ISB	Date:02/03/0915K Outcome Death					Death		nate:02/05/09ISR Number:		Death	Date: 02/02/02/02	Date: 02/05/09ISR
			p√ Cardio-Respiratory Arrest	nata-02/05/0915R Number: 6067681-OReport Type:Expedited (15-DaCompany Report MUS-MATSON-2009-00818	PT Cardio-Respiratory Arrest	Transferredited (15-DaCompany Report #US-WATSON-2009-00814				Cardio-Respiratory Arrest		Number: 6067613-5Report Type:Expedited (15-DaCompany Report #US-WATSON-2009-00622		Death	D	nara: 17765/0915R Number: 6067601-9Report Type:Expedited (15-DaCompany Report #US-WATSON-2009-00675
			Report Source	dited (15-DaCompany F	Report Source	dited (15-DaCompany R					Report Source	lited (15-DaCompany Re		,	Report Source	ited (15-DaCompany Re
Hydrocodone Bitartrate/Acetomino phen Unknown Strength (Watson) Marijuana	Laboratories) Clonazepam (Watson Laboratories)	(Watson Laboratorics) Diphenhydramine	Product Sertraline Hydrochloride	Report #US-WATSON-2009-00	Product Alprazolam (Watson Laboratories) Heroin Methadone Quetiapine	EDOIC #US-WATSON-2009-008	/00002701/ Quetiapine	Hydrochloride XI (Watson Laboratories) Aspirin	. Hand	Ibuprofen (Watson Laboratories) Hydrocodone	Product	sport #US-WATSON-2009-006	Hydrochloride XI Hydrochloride XI (Watson Laboratories) Quetiapine	Gabapentin (Watson Laboratories)	Product	port #US-WATSON-2009-006
នួន	S S	ru S	Role	818	Role SS SS	314	នួន	in in	Cr.	PS	Role	22	នួន	5	Role	75
Watson Laboratories	Watson Laboratories Watson Laboratories	Watson Laboratories	Manufacturer		Manufacturer Watson Laboratories			Watson Laboratories	Watson Laboratories	Watson Laboratories	Manufacturer		Watson Laboratories	Watson Laboratories	Manufacturer	
a	u o	•	Route	Age:32 YR	Route	Age:22 YR					Route	Age:55 YR			Route	Age:47 YR
UNK	UNK	unknown	Dose	Gender:Male	Dose unknown	Gender:Male		UNK	UNK	unknown	Dose	Gender:Female	UNK	unknown	Dose	Gender:Male
			Duration		Duration	I/FU:I					Duration	e I/FU:I			Duration	I/FU:I

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

Outcome Life-Threatening Hospitalization - Initial or Prolonged	7-1-00/06/0016B Night		Outcome Death	Date:02/05/09ISR Numb		Outcome Death	Date:02/05/09ISR Numbe	Date:02/05/09ISR Numbe Outcome Death	
PT Coma Overdose Sulcide Attempt	/00002701/ SS		PT Death	Date:02/05/0915R Number: 6067715-]Report Type:Expedited (15-DaCompany Report #US-WATSON-2009-00805		PT Cardio-Respiratory Arrest	Date:02/05/09ISR Number: 6067712-BReport Type:Expedited (15-DaCompany Report #US-WATSON-2009-00804	Date:02/05/09ISR Number: 6067705-OReport Type:Expodited (15-DaCompany Report #US-WATSON-2009-00799 Outcome PT Report Source Product Ibuprofen (Watson Laboratories) Death Death Laboratories) Outcome PT Outcome Product Ibuprofen (Watson Laboratories) Outcome Death Laboratories) Outcome Carbamazepine Carbamazepine Carbamazepine Lamorrigine	
Report Source	pedited (15-DaCompany Repr		Suffice of the suffic	pedited (15-DaCompany Repo		Report Source	sedited (15-DaCompany Repo	edited (15-DaCompany Repor	
Product Sertraline Quetiapine Denrodiacepine Paracetamol	/00002701/ prt #GB-RANBAXY-2009RR-	Verapamil (Watson Laboratories) Quetiapine Aspirin	Ibuprofen (Watson Laboratories) Gabapentin (Watson Laboratories)	Product	Strength (Masson Laboratories) Quetiapine Lithium Methadone	Product Diazepam (Watson Laboratories)	rt #US-WATSON-2009-0080	Product Purpose (Watson Laboratories) Lopzofen (Watson Laboratories) Lorazepam (Watson Laboratories) Quetiapine Carbamazepine Daloxetine Daloxetine Lamotrigine	Lithium Queriapine Methadone
Role PS SS	21517	ន ន	en en	Role	មេខេខ	Role	4.	9 Role	11 (A) (A)
Manufacturer Ranbasy Pharmaceuticals, Inc.		Watson Laboratories	Watson Laboratories Watson Laboratories	Manufacturer	Watson Laboratories	Manufacturer Watson Laboratories		Manufacturer Watson Laboratories Watson Jaboratories	
Route	Age:61 YR			Age:66 YR		Route	Age:61 YR	Age:56 YR	
Dose 3.1 g, UNK 4.3 g, UNK	Gender:Male	UNK	unknown UNK	Gender:Female	UNK	unknown [Gender:Female	Gender:Female Dose D unknown UNK	UNK UNK
Duration	I/FU:I			1/fU:I Duration		Duration	I/EU:I	I/FU:I Duration	

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

ORAL)

Date:02/11/09ISR Number: 6073036-5Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2009UW03582	
Age:86 YR Gender:Female	

Outcome Death	Date:02/11/09ISR Numb	Outcome Hospitalization - Initial or Prolonged	Date:02/11/09ISR Numb	Outcome Death	Date:02/11/091SR Numb	Outcome Death	Date:02/11/09ISR Numbe	Date:02/11/09ISR Numbe Outcome Death Life-Threatening Life-Threatening Outcome Poly11/09ISR Numbe Outcome Hospitalization - Initial or Prolonged	
PT Overdose	Date:02/11/D9ISR Number: 6073202-9Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2009UWD1411	FT1 Fall Hospitalisation Lower Limb Fracture	Date:02/11/09ISR Number: 6073173-5Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2009UW03625	PT Therapeutic Agent Toxicity	Dare:02/11/091sR Number: 6073165-6Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2009UW03792	PT Death	Date:02/11/09ISR Number: 6073163-2Report Type:Expedited (15-DaCompany Report #BR-ASTRAZENECA-2009UW03612	Date:02/11/09ISR Number: 6073036-5Report Type:Expedited (15-DaCompany Report Burce Product Pathorate Product Produ	
Report Source	pedited (15-DaCompany R	Report Source	pedited (15-DaCompany Ro	Report Source	pedited (15-DaCompany Re	Report Source	pedited (15-DaCompany Re	edited (15-DaCompany Re Report Source Report Source	
Product Seroquel Methadone	eport #US-ASTRAZENECA-20	Product Seroquel	eport #US-ASTRAZENECA-20	Product Seroquel	port #US-ASTRAZENECA-20	Product Seroquel	port #BR-ASTRAZENECA-20	port #US-BRISTOL-MYERS Seroquel Seroquel Namenda Product Product Product Ability Tabs 10 Mg Seroquel Xanax Lithium Prozac Ambien	
Role Manufacturer PS SS	009UW01411	Role Manufacturer PS	009UW03625	Role Manufacturer PS SS	70YUW03792	Role Manufacturer PS	109UW03612	Role Manufacturer PS SS C C Role Manufacturer PS SS	0011003582
Route ORAL	Age:	Route ORAL	Age:	Route ORAL ORAL	Age:9889 I	Route ORAL	Age:	Route ORAL ORAL Age:54 YR	Age: 86 YR
Dose	Gender:Male	Dose	Gender:Female	Dose	DY Gender:Male	Dose	Gender:Male	Dose Gender: Male Dose every night 1 Dosage form= 40 (Units not specified)	Gender:Female
Duration	I/FU: F	Duration		Duration 8 YR 8 YR	I/FU:I	Duration	I/FU:I	Dura 3	1/60:1

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Other

·		Cher	Outcome Death	Date:02/24/09I		Outcome	Date:02/24/09I	Outcome	Date:02/24/09I		Outcome Death	Date:02/23/09Is			
			PT Completed Suicide	Date:02/24/09ISR Number: 6089032-8Report Type:Expedited (15-DaCompany Report #A0T69523A	White Blood Cell Count Decreased	PT Neutrophil Count Decreased	Date:02/24/09ISR Number: 6088957-7Report Type:Expedited (15-DaCompany Report #AU-ASTRAZENECA-2009APD1373	PT Platelet Count Decreased White Blood Cell Count Decreased	Date:02/24/09ISR Number: 6088512-9Report Type:Expedited (15-DaCompany Report #CA-ASTRAZENECA-2009UW00170		PT Death	Date:02/23/09ISR Number: 6093796-7Report Type:Direct			
			Report Source	pedited (15-DaCompany R		Report Source	pedited (15-DaCompany R	Report Source	pedited (15-DaCompany R		Report Source				Critica
Metoprolol Remeron Seroquel Tramadol	Cyclobenzaprine Klonopin	Alcohol Ativan	Product Paxil	Report #A0769523A	Scroquel	Product Seroquel	eport #AU-ASTRAZENECA-2	Product Seroquel Novo-Quetiapine	eport #CA-ASTRAZENECA-2	Seroquel 300 Mg	Product Methadone 10 Mg	Company Report #CTU 367171	Seroquel /01270901/ (Seroquel Quetiapine) (Not Spocified)	(Temesta Lorazepam) (Not Specified)	Product
ស ស ស ស ស ស ស ស	សស	ប ប ប	Role PS		ន	Role PS	009AP013	Role PS SS	TOOMUGOO	ts Cs	Role PS		SS	S)	Role
		Glaxosmithkline				Manufacturer	73	Manufacturer	70		Manufacturer				Manufacturei
ORAL ORAL ORAL ORAL	ORAL ORAL	ORAL	Route ORAL	Age:49 YR	ORAL	Route ORAL	Age:62 YR	Route ORAL UNKNOWN	Age:	ORAL	Route ORAL	Age:39 YR	ORAL	ORAL	Route
required 45MG Per day 300MG Per day	2MG As	2MG Twice per dav	Dose 30MG Twice per day	Gender:Male	22	Dose TAKEN AS WELL AS SOMG TWICE	Gender:Female	Dose	Gender:	TIM PO 1,500 MG BED TIME PO	Dose 10 MG 2 DAILY, 2 BED	Gender:Female	(300 MG QD ORAL)	(2 MG QD ORAL)	Dose
Ψ.		н	Duration	1/fU:F		Duration L E	1/FU:I	Duration 5 YR	I/FU:F	6 XH	Duration	I/FU:I			Duration

Date:02/27/09ISR Num Outcome Hospitalization - Initial or Prolonged	Date:02/27/09ISR Nu Outcome Other	Date:02/27/09ISR Num Outcome Hospitalization - Initial or Prolonged	Date:02/27/09ISR Num Outcome Hospitalization - Initial or Brolonged	Date:02/27/09ISR Num Outcome	Date:02/27/09ISR Numl Outcome
Date:02/27/09IGR Number: 6096685-7Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2009UW05059 Outcome PT Report Source Product Role : Hospitalization - Panic Attack PS	Date:02/27/0918R Number: 6096617-1Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2009UW05076 Outcome PT Report Source Product Role i Other Blood Glucose Increased Seroquel Xr PS Systemic Lupus Erythematosus	Date:02/27/09ISR Number: 6096523-2Report Type:Expedited (15-DaCompany Report #CH-WYE-G03161909 Outcome PT Report Source Product Hospitalization - Drug Interaction Thentional Overdose Ethanol Restless legs Syndrome Ethanol Effexor Serequel Wethadone	<pre>Date:02/27/09ISR Number: 6096441-XReport Type:Periodic Outcome PT Hospitalization - Rash Initial or Prolonged Stevens-Johnson Syndrome</pre>	Date:02/27/09ISR Number: 6096418-4Report Typc:Periodic Outcome PT Drug Interaction Sedation	Date:02/27/09ISR Number: 6096036-8Report Type:Periodic Outcome Drug Interaction Palpitations
Expedited (15-DaCompa Report Source	Expeditod (15-DaCompa Report Source d	eport Source:	Report S	Report 5	Report S
nny Report #US-ASTRAZENEC Product Seroquel	ny Report MUS-ASTRAZENECA : Product Seroquel Xr	ny Report #CH-WYE-G031619 Product Temesta Ethanol Ritalin Efexor Seroquel Wethadone	Company Report #A0761411A Fource Product Lamictal Lamotrigine Seroquel	Company Report #A0760260A Source Product Lamictal Ambien Seroquel	Company Report #A0742634A Forduct Lamictal Quetiapine
₁-2009U₩0505 Role PS	∿-2009UW0507 Role PS	09 Role PS II	Role PS SS	Role PS SS	ss to Rolle
)59 • Manufacturer	. Manufacturer	Manufacturer Wyeth Pharmaceuticals Inc. Unknown Ciba-Geigy Wyeth Pharmaceuticals Inc. Zeneca Unknown	Manufacturer Glaxosmithkline Glaxosmithkline	Manufacturer Glaxosmithkline	Manufacturer Glaxosmithkline
Age:43 YR Route ORAL	Age: Route ORAL	Age:42 YR Route ORAL ORAL ORAL ORAL ORAL ORAL	Age: Route ORAL ORAL	Age:58 YR Route ORAL ORAL	Age: Route ORAL
Gender:Female Dose	Gender: Dose	Gender: Female Dose	Gender:Female Dose 100MG Per day 100MG Per day	Gender:Female Dose	Gender:Female Dose
e 1/fU:I Duration	I/EU:I	I/EU:I Duration 1 DAY	I/FU:T Duration y	I/FU:I Duration	I/FU:I Duration

Date:02/27/09ISR Num Outcome Death	Outcome Death	Date:02/27/09ISR Nun	Outcome Life-Threatening Hospitalization - Initial or Prolonged	Date:02/27/09ISR Num		Outcome Death	Date:02/27/09ISR Num	Outcome Death	Date:02/27/09ISR Numl
Date:02/27/09ISR Number: 6107373-ZReport Type:Periodic Outcome PT Death	PT Drug Toxicity	Date:02/27/09ISR Number: 6105279-6Report Type:Periodic	PT Respiratory Depression	Date:02/27/09ISR Number: 6105254-lReport Type:Periodic		PT Asphyxia Completed Suicide	Date:02/27/09ISR Number: 6104089—3Report Type:Expedited (15-DaCompany Report #1000004856	PT Drug Toxicity Malaise	Date:02/27/09ISR Number: 6101101-2Report Type:Expedited (15-DaCompany Report #BAR_02851_2009
Report S Health Professi	Report S Health Professi		Report Source Health Professional			Report Source Foreign Health Professional	Hited (15-DaCompany Rep	Report Source Literature Health Professional	lited (15-DaCompany Rep
company Report #Rem_uzin_zove Froduct Buprenorphine Methocarbamol Zonisamide Quetiaphn Ethanol	Buprenorphine Buprenorphine Nordiazepam Quetiapine	Company Report #RB-8991-2008	Product Suboxone Clozapine Lithium Cymbalta Seroquel Topamax	Company Report #RB-2299-2008	Seroquel (200 Milligram, Tablets)	Product Escitalopram (Escitalopram (Escitalopram Oxalate) (Tablets)	ort #1000D04856	Product Diazepam Quetiapine Methadone Dextromethorphan rormethazine Nordiazepam	ort #BAR_02851_2009
801e 95 55 55	SSS	,	SS SS SS PS SS SS SS SS SS SS SS SS SS S		S	Role Ps		Role PS SS SS SS	
Manufacturer	משוחד מררחדם ד		Manufacturer			Manufacturer		Manufacturer	
Route	Age: 36 YR	Age:39 YR	Route ORAL ORAL ORAL ORAL ORAL	Age:34 YR	ORAL	Route	Age:30 YR	Route	Age: 48 YR
Do ss e	Gender:Female	Gender:Female	Dose B MG ORAL ORAL ORAL ORAL	Gender:Female	600 MG (600 MG, 1 IN 1 D), ORAL	Dose 20 MG (20 MG, 1 IN 1 D)	Gender:Male	Dose Dr Dr Dr	Gender:Female
Dur		n I/FU:I	Duration	; I/FU:I		Duration	I/FU:I	Duration	1/FU:1

	Outcome PT Report Source Hospitalization - Loss Of Consciousness Initial or Prolonged	Date:03/02/09ISR Numbor: 6098733-TReport Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2009UW05414	Outcome PT Report Source Hospitalization - Drug Eruption Initial or Prolonged	Date:03/02/0915R Number: 6098704-OReport Type:Expedited (15-DaCompany Report #TR-ASTRAZENECA-2009SE00909		Date:03/02/09ISR Number: 6098675-7Report Type:Expedited (15-DaCompany Report #US-TYCO HEALTHCARE/MALLINCKRODT-T200905343	Outcome PT Completed Suicide	Date:03/02/03ISR Number: 6098666-6Report Type:Expedited (15-Dacompany Report #US-TYCO HEALTHCARE/MALLINCKRODT-T200900334	Outcome PT Report Source Product Role Manufacturer Death Cardio-Respiratory Arrest Fluoxetine SS Tyco Healthcare Completed Suicide Garisoprodol SS Tyco Healthcare Carlsoprodol SS Propranolol SS Propran
Klonopine C Claritin D C Zyrtec Remeron C Gemfibrozil C	Product Seroquel Methadone Flexeril Phenergan Paxil	pany Report #US-ASTRAZENECA-2009UW0541	ce Product Role Seroquel PS Depakin C	pany Report #TR-ASTRAZENECA-2009SE0090	ce Product Role Hydrocodone/Acetamin Sphen Outtiapine SS Morphine SS	pany Report #US-TYCO HEALTHCARE/MALLIN	re Product Role Tramadol PS Acctaminophen SS Carisoprodol SS Quetiapine SS Quetiapine SS Quetiapine SS Quetiapine SS Thacdone SS Fexofendine SS Thyroid Preparations SS Clonazepam SS Ethanol SS Opoids	»any Report #US-TYCO HEALTHCARE/HALLING	e Product Role Oxycodone PS Fluovetine SS Carisoprodol SS Propranolol SS Citalopram SS Quetiapine SS
	Manufacturer Route ORAL		Manufacturer Route ORAL	9 Åge:	Manufacturer Route Tyco Healthcare ORAL ORAL	CKRODT-T200900343 Age:40	Manufacturer Tyco Healthcare ORAL ORAL ORAL ORAL ORAL ORAL ORAL ORAL	;KRODT-T200900334 Age:39	Manufacturer Route Tyco Healthcare ORAL Tyco Healthcare ORAL ORAL ORAL
	, e	Age:49 YR Gender:Female	Dose 2×1	Gender:Male	Dose	:40 YR Gender:Female	Da s c	39 YR Gender:Female	Dosc
Page: 4742		I/FU:I	Duracion 15 DAY	1/FU:I	Duration	I/FU:T	Duration	I/FU:I	Duracion

				Outcome Hospitalization - Initial or Prolonged		nataona/ns/jigisa Numbe										Initial or Prolonged	Hospitalization -	Outcome	Date:03/05/09ISR Number:		OCHET	Outcome	Date:03/05/0915R Number	
				Pri Drug Interaction Intentional Overdose Restless Legs Syndrome		nsta.on/Anglisk Number: 6108691-4Report Type:Expedited (15-DaCompany Report #DSA_33273_2009						Multiple brug Overdose	Drug Toxicity	Dizziness	Consciousness	Come Scare Adjustment	Blood Pressure Decreased	PT	r; 6108662-8Report Type:Expedited (15-DaCompany Report #JFI-P-005723		Tongue Disorder	PT	Date:03/05/09ISR Number: 610/978-9Report Type:Direct	
				Foreign Health Professional	Report Source	ited (15-DaCompany Rep									Other	Professional	Foreign	Report Source	ited (15-DaCompany Repo			Report Source		
Seroquel /01270902/ (Seroquel Quetiapine Fumarate) (Not Specified) Ritalin Alcohol	Methadone (Methadone)	Efexor (/1233802/ (Efexor - Venlafakine Hydrochloride) (Not Specified)	•	Temesta /00273201/ (Temesta - Lorazepam) (Not Specified)	Product	ort #DSA_33273_2009	Loxoprofen Sodium	Hydrochloride	Hydrochloride	Trazodone	Clonazepam	Triazolam	Flunitrazepam	Brotizolam	Quetiapine Fumarate	Maleate)	(Fluvoxamine	Product	et #JPI~P-005723	1000	Seroquel Zoloft Klanapin	Product Abilify		Company Report WCTU 368370
	SS	ន		PS	Role		n	n	SS	,	n in	23	SS	n u	S	PS		Role		:	សសស	Role		
					Manufacturer													Manufacturer				Manufacturer		
ORAL	ORAL	ORAL		ORAL	Route	Age:			OHAL		ORAL	ORAL	ORAL	ORAL	ORAL	ORAL		Route	Age:23 YR			KOULE		Age:
200 MG QD, GRAL	120 MG QD, ORAL	150 MG QD, ORAL	THE PRESCRIBED AMOUNT, ORAL	25 MG 1X, NOT	Dose	Gender:Female			ORGE		ORAL	ORAL	ORAL	ORAL	ORAL	ORAL		Dose	Gender:female			i con	•	Gender:Female
			r)T)	Duration	I/FU:I												Duration						I/FU:I

Date:03/23/09ISR N Outcome Death	Date:03/23/09ISR Ni Outcome Other	Date:03/23/09ISR Num Outcome Hospitalization - Initial or Prolonged	Date:03/20/09ISR Num Outcome Other Other Other Other Date:03/23/09ISR Num Outcome Other	Date:03/20/09ISR Num Outcome Hospitalization - Initial or Prolonged
Date:03/23/09ISR Number: 6128387-2Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2009UW07221 Outcome PT Report Source Product PS Death Death C Hethadone C Lyrica C	Date:03/23/0915R Number: 6128276-3Report Type:Expedited (15-DaCompany Report #NL-ASTRAZENECA-2009AC00901 Report Source Product PS Seroquel PS Other Convulsion C Simvastatine C Simvastatine C Otypes Drug Interaction C Otypes Drug Interaction C Otypes Drug Interaction C	Date:03/23/09ISR Number: 6127926-5Report Type:Expedited (15-DaCompany Report #CH-ASTRAZENECA-2009PK00859 Outcome PT Report Source Product Role PS Seroquel SS SE	Date:03/23/09ISR Number: 6128879-6Report Type:Expedited (15-DaCompany Report #14518963) Outcome	Date:03/20/09ISR Number: 6127024-OReport Type:Expedited (15-DaCompany Report #PHHY2009DE08913 Outcome
pedited (15-DaCompany F Report Source	padited (15-DaCompany R Report Source	pedited (15-DaCompany R Report Source	edited (15-DaCompany Re Report Source Health Professional Company Representative Representative Report Source Report Source	edited (15-DaCompany Re Report Source
Report #US-ASTRAZENECA- Product Seroquel Xr Methadone Lyrica	teport #NI-ASTRAZENECA- Product Seroquel Thysax Duotab Simvastatine Diphantoine-2	eport #CH-ASTRAZENECA-: Product Seroquel Seroquel Seroquel Seroquel Seroquel	aport #14518963 Product Emsam Abilify Seroquel Seroquel Product Seroquel Synthroid	port #PHYY2009DE08913 Product Carbamazepine Risperidone Zolpiden Quetiapine
-2009UW07221 Role Manufacturer PS C C	2009AC00901 Role Manufactuzer PS C C I	2009PK00859 Role Manufacturer PS SS SS SS SS SS	Role Manufacturer PS SS SS SS SS CO090W06918 Role Manufacturer PS C	Role Manufacturer PS Novartia Sector: Pharma C
Age:32 YR Route OKAL	Age:18713 Route ORAL ORAL ORAL ORAL ORAL	Age:13 YR Route ORAL ORAL ORAL ORAL ORAL	Age: Route Route Age: 82 YR Route ORAL	Age: 44 YR Route
Gender:Female Dose	Age:18713 DYGender:Female Le Dose	Gender:Female Dose	Dose 5 MILLIGRAM 5 MILLIGRAM Dose Gender: Female	Gender: Female Dose 600 mg, UNK 8 mg, / day 10 mg/ UNK 700 mg/d
e I/FU:I Duration	1/FU:I Duration	I/FU:I DIRATION A DAY B DAY B DAY B DAY B DAY B DAY	Dura	I/FU:I Duration

		Date:10/12/0918 Outcome Other	Date:10/12/0915 Ourcome Death Other	Other	Death Other Other Date:10/09/09/15	Date:10/09/09ISR Number:	Date:10/09/09ISF Outcome Death
	Inadequate Control Diabetic Neuropathy Type 2 Diabetes Mellitus	Dare:10/12/0915R Number: 6396223-5Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2006UW27948 Outcome FT Report Source Eroduct Role PS Seroquel PS Other Diabetes Mellitus Seroquel SS Other Diabetes Mellitus Ahlifo G	Date:10/12/0915R Number: 6396222-JReport Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2009DW10693 Outcome PT Report Source Product PS Death Diabetic Come Ability C Other Type 1 Diabetes Wellitus Thorazine C	Agitation Anger Anger Drug Clearance Increased Drug Effect Decreased Impulse-Control Disorder Initial Insummie Irritability	Death Vest: Ordose Kethadone SS Other Overdose SS Other HUS-ASTRAZENECA-2009UMI5018	\ Number: 6395758-9Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-20095E179€1 Product Role Product Role Proth	Date:10/09/09ISR Number: 6395635-3Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2009SE17957 Outcome PT Report Source Product Role Death Death
		pedited (15-DaCompany Report Source	pedited (15-DaCompany F Report Source	Report Source	sedited (15-DaCompany R	edited (15-DaCompany R Report Source	edited (15-DaCompany R Report Source
Cyclobenaprine Cyclobenaprine Aspirin Flexeril Tylenol	Buspar Effexor Prevacid Enalapril Lantus	Report #US-ASTRAZENECA- Product Seroquel Seroquel Abilify	Report #US-ASTRAZENECA- Product Seroquel Ability Thorazine	Product Seroquel Xr Seroquel Xr	Hethadone eport #US-ASTRAZENECA-:	eport #US-ASTHAZENECA-; Product Scroquel Xr	aport #US-ASTRAZENECA-2 Product Seroquel
0000	, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	-2006UW2794B Role Manufacturer PS SS G	.2009UW10691 Role Manufacturer PS C C	Role Manufacturer PS SS	Pharmaceuticals S5 20090W15018	2009SB17961 Role Manufacturer PS Astrazeneca	20093E17957 Role Manufacturer PS Zeneca Pharmaceutical
ORAL	SUBCUTANEOUS	Age:540 M Route ORAL ORAL	Route ORAL		ORAL UMKNOWN Age:5 YR	Age: Route	Age:384 MO Route DRAL
81 MG, 325 MG ONE TO TWO P.O. Q.4 TO 6 HOURS P.R.N., ONE TABLET THREE TIMES A	30-60 MG 75-375 MG 86 UNITS AT BEDTIME, 100 UNIT/ML	MON Gender:Male Dose 150-300 MG 150-300 MG	Dose	Dose	Gender:Male	Gender:Male Dose	MON Gender:Female Dose
, , , , , , , , , , , , , , , , , , ,	c ·	I/FU: F Duration 51 MON 51 MON	Duration	Duration	1/FU:F	1/E	I/FU:I Duration

Freedom Of Information (FOI) Report

Date:10/29/09ISR Nu		Outcome	Date: to/ 29/0513% No	20 / 20 / 20 / 20 / 20 / 20 / 20 / 20 /				Other		Date: 10/29/09ISR Num	Death		Date:10/29/09ISR Num	100000000000000000000000000000000000000	Hospitalization -	Outcome	Date:10/29/09ISR Num													
mber: 6420453-7Report Type		PT Death		mber: 64 9961-4Report Type	Weight Increased	Tardive Dyskinesia	Loss Of Consciousness	Convulsion	7	mber: 64195768Report Type	Completed Suicide Overdose	P.T.	mber: 6419379-4Report Type		Ketoacidosis	PT	ber: 6419356~JReport Type:													
Date:10/29/0915R Number: 6420453-7Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-20095E21569		Report Source		re				•	Report Source	Date:10/29/09ISR Number: 6419576-8Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2009SEZ1262		Report Source	Date:10/29/09ISR Number: 6419379-4Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2009SE22137			Report Source	Date:10/29/09ISR Number: 6419356-3Report Type:Expedited (15-DaCompany Report #JP-ASTRAZENECA-2009SE22555													
Report #US-ASTRAZENECA-	Methadone	Product		Report #US-ASTRAZENECA-2		Depakote	Lamictal	Seroquel	Product	eport #US-ASTRAZENECA-2	Seroquel Xr Depakote	Product	eport #US-ASTRAZENECA-2	Risperidone	of the state of th	Product	eport #JP-ASTRAZENECA-2		Zolpidem	Geodon	Fluconazole	Furosemide	Procrit	Avandia	Diovan	Amitriptyline	Lyrica Lyrica	Byetta	Hyoscyamine	Loperamide Hcl
2009SE215	ts ts	PS	,	009SE228		n	ი	P S	Role	009SEZ12	מים	Role	009SE221	n	٠ ;	Role	0095E225		a	מו	י נ	a 0	c	ი ი	ດ	n	חי	າຕ	n	n
69	110000			05				Zeneca Pharmaccutical	Manufacturer	62		Manufacturer	37		Pharmaceutical	Manufacturer	15													
Age:		ORAL	2	Age:		UNKNOWN	UNKNOWN	ORAL	Route	Age:21 YR	CIGNE	Route OBAT.	Age:23 YR		ORAL	Route	Age:35 YR				ORAL	INKNOWN	UNKNOWN	UNKNOWN	CNENCEN	UNKNOWN	UNKNOWN	UNKNOWN	UNKNOWN	(INHALATION) UNKNOWN
Gender:Female			Dose	Gender:Male					Dose	Gender:Male		Dose	Gender:Male			Dose	Gender:Male										50MG-100MG			
e 1/FU:I			Duration	I/FU:I					Duration	I/FU:I		Duration	I/FU:I			Duration	1/FU:1	• > 7 - 7		4 YR										

Outcome proposed programmer proposed programmer professional professio

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FDA - Adverse Event Reporting System (AERS)

	Freedom Of Information (FOI) Report ne SS Levonorgestrel SS Excedin SS Iron C Supradyn C Caffeine C Glaxosmithkline
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Gender:Female	1
I/FU:I	DAY

Outcome PT Report Source Other Consciousness Aphasia Confusional State Dysarthria Eye Disorder Insomnia Lethargy Somnolence	Date:11/06/09ISR Number: 6431247-OReport Type:Expedited (15-DaCompany Report #US-PffZER INC-2009290013	Date:11/06/0915R Number: 6431031-8Report Type:Expedited (13-backmyen) Report Tource Product Role . Outcome PT Report Source Seroquel Xr PS	115-Di	Date:11/06/0915K NUMBER: 0930557 Neport Source Outcome PT Accidental Overdose Death Aspiration Respiratory Arrest	17. CC (POTC) Number: CARDARA-Remort Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2009SE17961	Outcome PT Report Source Hospitalization - Adverse Event Initial or Prolonged Drug Interaction Hospitalisation Rhabdomyolysis	Datc:11/06/09ISR Number: 6430857-4Report Type:Expedited (15-DaCompany Report #DE-MERCK-0911DEU00008	Outcome PT Report Source Lospitalization - iarge Intestine Initial or Prolonged Perforation	Date:11/06/09ISR Number: 6430719-ZReport Type:Expedited (15-DaCompany Report #US-ASTRAZEKECA-2009SE23935	
Source Product Geodon Seroquel	aCompany Report #US-PFIZER INC-200929	Source Product Seroquel Xr	aCompany Report #US-ASTRAZENECA-2009S	Source Product R. Sernquel P. Hethadone S. Clonopin C	aCompany Report #US-ASTRAZENECA-2009SI	Source Product F Vyrorin Quetiapine Fumarate S	:Company Report #DE-MERCK-0911DEU00008	ource Product P Scroquel E	Company Report #US-ASTRAZEKECA-2009SE	Levenorgestrel 55 Excedrin 55 Iron 6 Supradyn 6 Caffeine 6
Role Manufacturer SS Pfizer, Inc. SS	0013	PS Astrazeneca Pharmaceuticals	224130	Role Manufacturer PS SS C C	17961	Role Manufacturer PS Merck & Co., Inc SS		Role Manufacturer P5 Zeneca Pharmaceutical	23935	Glaxosmithkline
ROULT	Age:	Route ORAL	Age:	ROULE ORAL ORAL ORAL ORAL	Age:17203	Route ORAL ORAL	Åge:	Route ORAL	Age:	UKNOWN UNKNOWN UNKNOWN UNKNOWN
Do as e	Gender:Female	Dose	Gender:	Dose	Age:17203 DYGender:Male	Dase	Gender:Male	Dose	Gender:Female	
Duration		Duration	I/FU:I	Duration 2 DAY	1/FU:F	Duration	1/FU:I	Duration		1 DAY

Date:01/11/10ISR Number: 6532811-OReport Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2010SE00900 Outcome PT Report Source Product Role Outcome PS	Date:01/11/10ISR Number: 6532807-9Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2009SE30536 Outcome PT Report Source Product PS Other Dystonia Seroquel Xr SS Seroquel Xr SS	Date:01/11/10ISR Number: 6532790-6Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2010SE00891 Outcome PT Report Source Product Role Completed Suicide P5 Drug Toxicity Methadone SS	Date:01/11/10ISR Number: 6532789-XReport Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2010SE00899 Outcome PT Report Source Product Role Death Completed Suicide PS Death Drug Toxicity Charcoal SS	Date:01/11/10ISR Number: 6532749-9Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2010SE00884 Outcome PT Report Source Product Role of Completed Suicide Outlapine PS Death Drug Toxicity Lorazepam SS	Outcome PT Report Source Product Role Completed Suicide PS Report Source Quetlapine PS Renzoliazepine PS Report Source Report PS Report Source Propoxyphene SS Rethadone SS Venlafare SS Venlafare SS Venlafare SS Venlafare SS Venlafarine SS Venla
pe:Expedited (15-DaCompany Report Source	pe:Expedited (15-DaCompany Report Source	se:Expedited (15-DaCompany i Report Source	не:Expedited (15-DaCompany F Report Source	e:Expedited (15-DaCompany Report Source	Report Source
Report #US-ASTRAZENECA-2 Product Quetiapine	Report #US-ASTRAZENECA-2 Product Seroquel Xr Seroquel Xr Seroquel Xr	Report #US-ASTRAZENBCA-2: Product Quetiapine Mathadone	Report #US-ASTRAZENECA-21 Product Ouetiapine Charcoal	Aeport #US-ASTRAZENECA-20 Product Quetiapine Lorazepam	Product Quetiapine Benzodiazepine Oxycodone Methadone Propoxyphene Priopoxyphene Antidepressant Varenicline Venlafaxine Lithium
0105E00900 Role Manufacturer PS Zeneca Pharmaceutical	009SE3U536 Role Manufacturer PS SS SS	0105E00891 Role Manufacturer PS Zeneca Pharmaceutical SS	010SED0899 Role Manufacturer PS Zeneca Pharmaceutical	0105E00884 Role Manufacturer PS Zeneca PS Pharmaceutical SS	Role Manufacturer PS Zeneca Pharmaceutical SS
Age: 47 YR Route ORAL ORAL	Age:44 YR Route ORAL ORAL ORAL	Age:55 YR Route ORAL ORAL	Age:53 YR Route ORAL	Age:57 YR Route ORAL ORAL	Route ORAL ORAL ORAL ORAL ORAL ORAL ORAL ORAL
Gender:Female Dosc	Gender: Female Dose	Gender:Male Dose	Gender:Male Dose	Gender:Female Dose	Dose
le 1/FU:I Duration	le I/FU:I Duration	I/FU:I Duration	I/FU:I Duration	e I/FU:I Duration	Duration

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FDA - Adverse Event Reporting System (AERS)

Date:01/11/10ISR Number: 6532942-SReport Type:Expedited (15-Daccompany Report #US-ASTRAZENECA-2010SE00/46 Outcome Pr Report Source Product P5 Zeneca Quetiapine P5 Zeneca OPAL Hospitalization - Drug Toxicity Hospitalization - Drug Toxicity Finitial or Prolonged Respiratory Arrest Benzodiazepine SS OPAL OPAL OPAL CONTROL OPAL CO	Anufacturer Rout eneca Pharmaceutical ORAL ORAL	Date:01/11/10ISR Number: 6532847-XReport Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2010SE00915 A Outcome PT	Date:01/11/10ISR Number: 6532842-OReport Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2010SE00889 A Outcome PT Report Source Product PS Zeneca ONAL Death Completed Suicide Paradicity Disception SS Parameccutical ORAL Temazepam SS ONAL Acetaminophen SS ONAL	Zeneca Pharmaceutical
EMECA-2010SE00/45 Role Manufacturer PS Zeneca Pharmaceutical SS ine SS	NECA-2010SE00857 Role Manufacturer PS Zeneca Pharmaceutical SS Pharmaceutical SS	Manufacturer Zeneca Pharmaceutical	Manufacturer Reneca Pharmaccutical	Pharmaceutical
	Age:16 YR ROUTE ORAL ORAL ORAL ORAL	.ge:49 YR	ège:24 YR	ORAL ORAL ORAL
Dase	Gender:Female Dose	Gender: Wale Dose	Gender:Female Dose	
Duration	J/FU:I	1/EU:1 Duration	1/FU:I Duration	

Outcome Other	Date:03/08/10ISR Nur	Outcome Other	Date:03/08/10ISR Num		Outcome Hospitalization - Initial or Prolonged Other	Date:03/08/10ISR Num	Outcome Death	Dale:03/08/1015R Numi	Outcome Life-Threatening Hospitalization - Initial or Prolonged	Date:03/08/10ISR Numb
Pr Sommolence Suicide Attempt	Date:03/08/10ISR Numbor: 6618235-6Report Type:Expedited [15-DaCompany Report #JP-ASTRAZENECA-2010SE08252	PT Coma	Date:03/08/10ISR Number: 6617991-OReport Type:Expedited (15-DaCompany Report #JF-ASTRAZENECA-2010SE09372	Hallucination Headache Memory Impairment Syncope Weight Decreased		Date:03/08/10ISR Number: 6617960-OReport Type:Expadited (15-DaCompany Report #PHHY2010AR11388	PT Cardiac Arrest Hepatic Failure	Dale:03/08/1015R Number: 6617938-2Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2010SE05056	PT Exrapyramidal Disorder Serotonin Syndrome	Date:03/08/10ISR Number: 6617626-7Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2010SE02601
Report Source	pedited (15-DaCompany R	Report Source	pedited (15-DaCompany Re		Report Source	pudited (15-DaCompany Re	Report Source	oedited (15~DaCompany Re	Report Source	edited (15-DaCompany Rep
Product Seroquel Dogmaryl Toledomin Gasmotin Bromarepam Sepazon	eport #JP-ASTRAZENECA-2	Product Seroquel Risperdal Herbesser R Lasix	port #JP-ASTRAZENECA-20	Seroquel Diazepam	Product Exelon Patch	port #PHHY2010AR1138B	Product Seroquel Seroquel Celexa Methadone	port #US-ASTRAZENECA-20	Product Seroguel Xr Symbalia Lithium Other Unspecified Medications Described As A Bunch	port #US-ASTRAZENECA-201
Role PS C C	010SE08	Role PS C C)10SE09:	ຕູ	Role PS		Role PS SS C	105E050	Role PS SS SS	LOSEDZG
e Manufacturer	252	e Manufacturer Zeneca Pharmaceutical	372		Manufacturer Novartis Sector: Pharma		Manufacturer	56	Manufacturer	01
ROULE ORAL	Age:23 YR	Route ORAL ORAL ORAL ORAL	Age:77 YR		TRANS DERMAL	Age:	Route ORAL ORAL	Age: 40 YR	ROUTE ORAL ORAL UNKNOWN	Age:
Dose		0 0	Gender:Female		4.6 mg, QD, 1 patch daily 5 cm2	Gender:Female	Doge	Gender:Male	Dose	Gender: Female
Duration	1/FU: F	1 DAY			بر س 1 1 1 1 1		Duration	I/FU:F	Duration	I/EU:E

Page: 7922

FDA - Adverse Event Reporting System (AERS)

	Darc:06/11/1015R Numb Outcome Other	Date:06/11/10ISR Numbo Outcome Hospitalization - Instial or Prolonged		
	Datc:06/11/1015R Number: 6765930-4Report Type:Expedited (15-DaCompany Report #JP-BRISTOL-MYERS SQUIBB COMPANY-14754816 Outcome PT Other Abortion Report Source Product Role Manufacturer Abortion Abortion Abortion Abilify Tabs SS	Date:06/11/10ISR Number: 6765784-6Report Type:Expedited (15-DaCompany Report #IT-ASTRAZENECA-2010SE15651 Outcome PT Report Source Product Role : Nospitalization - Agitation PS Seroquel Xr PS Finitial or Prolonged Anxiety Report Source Product PS Finitial or Prolonged Anxiety Report Source Product Report Source Report Source Report Source Report Source Report Travor C		Renal Failure Sudden Cardiac Death Surgery
	pedited (15-DaCompany Re Report Source	pedited (15-DaCompany Re Report Source		Report Source
Abilify Tabs Abilify Tabs Miradol Miradol Miradol Miradol Lullan Lullan Lullan Seroquel Seroquel	port #JP-BRISTOL-MYERS Product Abilify Tabs Abilify Tabs	port #IT-ASTRAZENECA-20 Product Seroquel X: Seroquel X: Seroquel X: Methadone Tavor	Seroquel Seroquel Norco Clonazepam Midodrine Midodrine Midodrine Lavofloxacin Zosyn. Vancomycln Magnesium Sulfate Retorolac Hydromorphone Heparin Gobepentin Fentanyl Epoetin Alfa Amiodarone Calcium Acetate Albuterol Famortidine Dopamine Dobutamine	Product Seroquel
מ מ מוממממממ	SQUIBB COMPANY-14754816 Role Wanufacturer P5 SS)10sE15631 Role Manufacturer PS SS C C		Role Manufacturer PS
ORAL	Age:37 YR Route ORAL ORAL	Age:17965 L Route ORAL ORAL ORAL ORAL	ORAL ORAL ORAL ORAL INTRAVENOUS INTRAVENOUS SUBCUTANEOUS SUBCUTANEOUS ORAL SUBCONJUNCTIVAL	Route ORAL
Abilify tabs fing Abilify tabs Abilify tabs fing Tabs Tabs Tabs Tabs Tabs Tabs Tabs	Gender:Female Dose Abilify tabs 6mg Abilify tabs	Age:17965 DYGender:Female .e Dose	0.25-0.5 MG PRN 20000 UNIT 2000 MG/250 ML DRIP 250 MG/250 ML DRIP	Dose
й й 1	e I/FU:F Duration 5	e I/EU:E Duration 362 DAY 366 DAY 366 DAY	119 DAY 114 DAY 121 DAY 221 DAY 222 DAY 22 DAY 11 DAY 11 DAY 11 DAY 11 DAY 23 DAY 23 DAY 24 DAY 25 DAY 26 DAY 26 DAY 27 DAY 31 DAY 31 DAY 31 DAY 32 DAY 34 DAY 34 DAY 35 DAY 36 DAY 37 DAY 38 DAY 38 DAY 39 DAY 31 DAY 31 DAY 32 DAY 33 DAY	Duration

Freedom Of Information (FOI) Report

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														Hospitalization - Initial or Prolonged	Outcome	Date:06/18/10ISR Numbe		Other	Outcome Hospitalization -	Date:06/18/10ISR Numbe
													Type 2 Diabetes Mellitus	Hiood Cholesteror Increased Cardiovascular Disorder Nack Triury	PT	Date:06/10/10ISR Number: 6778806-3Report Typo:Expedited (15-DaCompany Report #US-ASTRAZENECA-2007UW12065	Diabetic Coma Lung Disorder Nervous System Disorder Overdose	Diabetes Mellitus	PT Anoxic Encephalopathy	Date:06/18/10ISR Number: 6778805-1Re ort Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2009UW03777
															Report Source	edited (15-DaCompany Ro			Report Source	edited (15-DaCompany Re
Cordarone		Ciaricin Lishnopril Venlafaxino	Terazosin Hcl		Nitedipine Simvastatin	Metoprolol	1,55001340]4	Indomethacin	Fosinopril	Fluozetine Hcl	Diazepam		Seroquel		Product Seroquel	eport #US-ASTRAZENECA-2	Dilantin Ambien Duvoid Melatonin Naprosyn	Xanax	Product Seroquel	eport #US-ASTRAZENECA-2
n		000	100		ar	n ()	ר		G	a	Ω		S		Role Manufacturer PS	2007UW12065	00000	n 0	SS BS Manutacenter	009UW03777
		ORAL	ORAL		ORAL	ORAL	ORAL	GRAL	ORAL				ORAL		Route ORAL	Age:19824	ORAL		ORAL	je:410
	BEDTIME FOR / NIGHTS THEN TAKE ONE TABLET BY	75 MG AT		HALF TABLET EVERY DAY IN EVENING	20 MG ONE			25 MG CAPSULE TAKE 1 OR 2 BY MOUTH THREE TIMES A	40 MG, 1/2 TABLET EVERY DAY	NEEDED 20-30 MG	5 MG AT BEDTIME AS	75 MG AT NIGHT FOR 7	DAYS THEN 50 25MG EVERY MORNING AND	MORNING AND 75 MG AT NIGHT FOR 7	Dose 25MG EVERY	Age:19824 DYGender:Male				MON Gender:Male
	Z Z	•		Z.	•			2 E	XX.		•		÷ 2	; - 0	Duration	1/fU:F		2 YR	8 X X B	I/FU:F

Seroquel
Raniidine (Con.)
Hethylin (Con.)
Cymbalta (Con.)
Fexofenadine (Con.)
Zolpidem (Con.)
Senokot (Con.)

Sanonous

Page: 8092

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Initial or Prolonged	Life-Threatening Hospitalization -	Distroppe	Date:07/09/10ISR Number								Initial or Prolonged	Outcome	;	Date:07/09/10ISR Number					Other	Death		Date:07/09/10ISR Number								
Administered Somnolence Syncope Toxic Encephalopathy	Accidental Overdose Incorrect Dose	P.T	Date:07/09/10ISR Number: 6840009-lReport Type:Expedited (15-DaCompany Report #2010Sp031964	Teartulness	Suicidal Ideation	Impaired	Psychomotor Skills	Decompensation	Payrhiatric	Daranoja	Depression	Anxiety	1	Date:07/09/1015R Number: 6827050-XReport Type:Expedited (15-DaCompany Report #CA-MERCK-1007USA00478				Sleep Disorder	Overdose	Drug Interaction	당기	Date:07/09/10ISR Number: 6826689-5Report Type:Expedited (15-Dacompany Report #US-PFTZER INC-2010077521								
Professional	Study Health	Report Source	dited (15-DaCompany Repo									700000000000000000000000000000000000000	Benort Source	dited (15-DaCompany Repo							Report Source	dited (15-DaCompany Repo								
Seroquel	Reg-Interferon Ribavirin	Product	ort #201059031964	Tenofovir	Ritonavir	Reyataz	Quetiapine Fumarate	Emtriva	Clonazepam	Citalopram	Bupropion Hydrochloride	Isentress	Product	rt #CA-MERCK-1007USA004	Coffee	Methadone	Nicotine	Chantix	Seroquel	Chantix	Product	rt #US-PFIZER INC-20100	Norvasc	Sinequan	Vicodin	Valium	Flexerit	:	Percocet	Glyburide
ា ហ្វេ ដ	n 151 m	Role		SS	S 1	in t	n u	S	SS	SS	S	Sa	Role	78	H +	→ ⊢	1 H	H	25	25		77521	n	C	C	G ·	חר)	n	n
		Manufacturer										Merck & Co	Manufacturer				Pfizer, Inc.			Pfizer, Inc.	Manufacturer									
ORAL	ORAL	Route	Age:56 YR	UNKNOWN	UNKNOWN	UNKNOWN	UNKNOWN	UNKNOWN	UNDNOWN	UNKNOWN	UNKNOWN	ORAL	Route	Age:44 YR						URAL	Route	Age:	ORAL			ORAL	ORAL	ORAT.	ORAL	ORAL
MG;QD;PO; 2400 MG;QD; PO 300 MG;HS; PO	1000 MG; QD; PO 2400	Dose 120 MCG; SC	Gender:Female										Dosa	Gender:Male	UNK	UNK	527	1 mg, UNK	UNK	1x/day		Gender: Male		DISPENSED	DISPENSED		30~25 MG	FRO	5/325 MG TID	5 MG BEFORE
0	Ð	Duration											Duration	I/FU:I							Duration	11011								

Outcome Other	Date:07/16/10IS		Outcome Other	Date:07/16/10ISF	Outcome Death Other	Outcome Death Date:07/16/1015R	Date:07/16/10ISR
pr Drug Exposure During Pregnancy Hypertension Pre-Eclampsia	Date:07/16/10ISR Number: 6848407-7Report Type:Expedited (15-DaCompany Report #DE-ASTRAZENECA-2010SE10824	Blood Glucose Increased Drug Dose Omission Intervertebral Disc Disorder Disorder Oropharyngeal Pain Prostate Cancer Somnolence Thyroid Disorder Tooth Disorder	PT Anderia Ander Antipsychotic Drug Level Increased Back Pain	Date:07/16/1015R Number: 6847604-4Report Type:Periodic	PT Drug Interaction Overdose Sleep Disorder	Outcome PT Report Source Product Rola Product Product PS Beroquel PS Seroquel SS Seroquel SS Remeron C Rozerem REMOVER REMOVER REMOVER REMOVED REM	Date:07/16/10ISR Number: 6847435-Skeport Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2008UH20440
Report Source	edited (15-DaCompany		Report Source		Report Source	Report Source	dited (15-DaCompany
Product Seroquel	Report #DE-ASTRAZENECA-	Lithium Neurontin Avapro Allopurinol Flurazapam Aspirin Percocet Percocet Promethazine Calcium Flax Seed Oil Antihypertensives	Product Seroquel Seroquel Seroquel Uroset K Clonazepam	Company Report #US-ASTRAZENECA-2010SE25452	Product Chantlx Coffee Seroqual Chantlx Methadone Nicotine Caffeine	Product Seroquel Seroquel Remeron Rozerem Rozerem Report #US-FFIZER INC-20	Report #US-ASTRAZENECA-2
Role Hanufacturer PS	2010SE10824	a a a a a a a a a a a a	Role Manufacturer PS SS CC C	2010SE25452	Role Manufacturer PS Pfizer, Inc. SS SS I Pfizer, Inc. I Pfizer, Inc. I Pfizer, Inc.	Role Manufacturer PS SS C C C	2008UW20440
ORAL ORAL	Age:		Route ORAL ORAL ORAL	Age:54 YR	Route CHAL	ORAL ORAL Age:	Age:
Dose	Gender:Female	DAY	Dose UNKNOWN DOSE TWO TIMES A	Gender:Male	Dose 0.5 mg, 1x/day UNK UNK 1 mg, UNK	100-600 ИG 100-600 ИG	Gender:Fcmale
Duracton			Duration 7 YR	I/EU:E	Duration	nuration	

Freedom Of Information (FOI) Report

Prozac C Wellbutrin C

Outcome PT Inappr Drug A Nausea Weight	Date:07/16/101SR Number: 6850216-XReport Type:Periodic	Outcome PT Death Dizzîne. Drog în Faligue Nightma. Overdos Sleep D	Date:07/16/10ISR Number: 684	Outcome PT Crying Hospitalization - Crying Initial or Prolonged Drug I Headac Migrai	Date:07/16/10ISR Number: 6849226-8Report Type:Periodic	Outcome PT Other Inmu Leve	Date:07/16/1015R Number: 6849141-XReport Type:Expedited (15-DaCompany Report #PHHY2010AT45731	Outcome PT Drug Int Hauses Tobacco Symptoms	Date.07/16/10ISR Number: 6848695-7Report Type:Periodic
opriate Schedule Of dministration Increased	50216-XReport Type:Periodic	Dreams s s c c s s s s s s s s s s s s s s s	Date:07/16/10ISR Number: 6849482-6Report Type:Expedited (15-DaCompany Report #US-ROXANE LABONATORIES, INC2010-RO-00858RO	nteraction he ne	19226-BReport Type:Periodic	PT Re Reug Interaction Immunosuppressant Drug Level Decreased	9141-XReport Type:Expedited	PT Re Drug Interaction Nausee Tobacco Withdrawal Symptoms	8695-7Report Type:Periodic
Report Source P	Company Report	Raport Source	(15-DaCompany Report	Report Source P. S. S. K. K. K. K. L.	Company Report	Report Source P: S:	(15-DaCompany Report	Report Source Pi	Company Report !
Product Chantix Tablets Seroquel Lasix Famotidine Lovastatin	Company Report #US-PFIZER INC-2007086831	Product Methadone Chantix Chantix Nicotine Gaffeine Gaffee Seroquel	#US-ROXANE LABORATORIE	Product Chantix Tablets I Chantix Tablets I Seroquel Klonopin Lexapro	Company Report #US-PFIZER INC-2007080965		#PHHY2010AT45731	Product R Chantix Tablets P Methadone I Procac I Provacid I Seroquel I	Company Report #US-PFIZER INC-2007075638
Role Manufacturer PS Pfizer, Inc. SS C C C	6831	Role Manufacturer PS Rozane Taboratories, SS Inc. SS	ES, INC2010-RO-00858RO	Role Manufacturer FS Pfizer, Inc. I I I)965	Role Manufacturer PS Novartis Sector: Pharma		Roie Manufacturer PS Pfizer, Inc. I Pfizer, Inc. I	63B
Route	Age:	Route ORAL ORAL	Age:20 YR	Route	Age:	Route	Age:	Route	Age:
Dose	Gender:Female	Dose 0.5 mg 1 mg	Gender:Male	Dose	Gender:Female	Dose	Gender:Male	Dose	Gender:Female
Duration	I/FU:I	Duration	I/FU:I	Duration	1/EU:F	Duration	1/FU:I	Duration	I/FU:I

7.1.0.									
	25 MG ON FIRST TWO	ORAL	Pharmaceuticals	ç	seroquer crotony		Aggression Suicidal Ideation	Other	
Duration	Dose	Route	Manufacturer	Role	Product	Report Source	PT	Outcome	
I/FU:I	Gender:Male	Age:27 YR	vp.)10SE3294	port #DE-ASTRAZENECA-20	Date:07/20/10ISR Number: 6961D94-7Report Type:Expedited (15-DaCompany Report #DE-ASTRAZENECA-2010SE32949	er: 6961094-7Report Type:	Date:07/20/10ISR Numbe	
5 DAY 22 DAY		ORAL ORAL ORAL	Pharmaceuticals Astrazeneca Astrazeneca	нн	Seroquel Seroquel			Cilia	
		ORAL	Wyeth Pharmaceuticals Inc. Janssen	H P	Efexor Risperdal		Akathisia Drug Interaction	Hospitalization - Initial or Prolonged	
Duration	Dose	Route	Manufacturer	Role	Product	Report Source	E	Ontcome Outcome	_
I/FU:F	Gender:Female	Age:30 YR			ort #CH-WYE-G05451010	nate in 1/20/1015g Number: 6860150-7Report Type:Expedited (15-DaGompany Report #CH-WYE-G05451010	r: 6860150-7Report Type:	nate:07/20/1015R Nimbe	_
				,	00		Sleep Disorder		
		UNKNOWN		 - }-	Nicotine		Overdose		
		UNKNOWN		• 🛏	Methadone		Nightmare		
		ORAL		н	Chantix		Falique		
		ORAL	E HOLLING COURT FOR F	H	Chantix		Dizziness	Other	_
		ORAL	<u>.</u>		Seroquel		Abnormal Dreams	Death	
Duration	Dose	Route	Manufacturer	Role	Product	Remort Source	7		
1/60:1	Gender:Male	Age:20 YR	J	105E33310	ort #US-ASTRAZENECA-20	Date:07/20/10ISR Number: 6859915-7Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2010SE33310	r: 6859915-7Report Type:E	Date:07/20/10ISR Numbe	_
				o r	Lovastatin				
	PRN PRN			าก	Neurontin				
	2-4 MG			ດ	Risperdal				
	5-10 MG			n	Zynrexa				
	50-300 MG	ORAL		വ	Trazodone	ŭ	Type 2 Diabetes Mellitus		
1000	20-40 MG	ORAL.		2 52	Seroquel		Gestational Diabetes		
59 MON	25-400 MG	•	Sample	ä	Seroquel	Report Source	PT Diabetic Neuropathy	Outcome Other	0 0
Distation		•		,		Date: 0//20/10/5K NUMDer: 603000-exchort type sybenred the natural section in the section of the	T: bessease-exepont type:	Date:0//20/1015K Numbe	
I/FU:F	Gender:Female	Age:40 YR	-	06UW08328	OFF #US-ASTRAZENECA-20	Topodited (15-Dafompany Ren			
				r	Welleti				
				חמ	Requip				
	PERCENTAGE			ი	Atrovent				
	1-1.5mg			n	Mirapex				
				ი	Allegra D				
	25-100 and 50-200			C	Sinemet				
	,			n •	Parlodel				
	75-150mg	ORAL		മറ	Effexor				
		OB A T		י נ	Soma				

Outcome	Date:07/28/10I	Outcome Other	Date:07/28/10IS	Outcome Death Other	Date:07/28/10IS				
PT Falique Insomnia Platelet Count Incressed Somnolence Weight Incressed Weight Incressed Wrong Technique In Drug Usage Process	Date:07/28/10ISR Number: 6879258-5Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2008UW03276	PT Neuroleptic Malignant Syndrome	Dare:07/28/1075R Number: 6878702-7Report Type:Expedited (15-DaCompany Report #80667249A	PT Drug Interaction Overdose Sleep Disorder	Date:07/28/10ISR Number: 6878309-XReport Type:Expedited (15-DaCompany Report #95-PFIZER 1NC-2010077521				
Report Source	adited (15-DaCompany Re	Report Source	dited (15-DaCompany Re	Report Source	dited (15-DaCompany Re				
Product Seroquel Seroquel Lunesta Lunesta Atenolol Enalapril	aport #U5-ASTRAZENECA-2	Product Frosinor Haloperidol Risperdal Seroquel Tiaprizal	port #80667249A	Product Chantix Coffee Seroquel Chantix Kethadone Nicotine Caffeline	port #US-PFIZER IMC-201	Tincture, Senna Alexandrina Fruit, Vitamedin (Benfortimmine) Rize (Clotiazepam)	pesyret (Irazowie Hydrochloride) Protecadin (Lafutidine) Alosen (Achillea Millefolium, Rubia Tinctorum Root	Goshajinkigan (Herbal Extract Nos) Yokukan-San (Herbal Extract Nos) Lendormin (Brotizolan)	Fumarate) Formulation Unknown
Role SS CC CC	оовичоз.	Pole SS SS SS		PS SS SS II	.0077521	იი ი	o 0	0 0 0	es es
e Manufacturer	276	Glaxosmithkline		Hanufacturer Pfizer, Inc. Pfizer, Inc. Pfizer, Inc. Pfizer, Inc.					
Route ORAL ORAL	Age:71 YR	ROUTE ORAL INTRAVENOUS ORAL ORAL INTRAVENOUS	Age:48 YR	ROUGE ORAL	Age:				ORAL
Doxe	Gender:Female	100MG per day 5MG per day 6MG per day 900MG per day 100MG per day	r:Female	Dose I D.5 mg, 1x/day UNK UNK 1 mg, UNK UNK	Gender:Male				ORAL
Duration	I/FU:F	143 DAY 1 DAY	I/FU:I	Duration	I/EU:F				