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.

1100 G Street, NW
Suite 900
Washington, DC
20005-3806
Phone: 202-347-1122
Fax: 202-347-1116

www.POGO.org
pogo@pogo.org

BACKGROUND

The dangers of Seroquel and methadone were first reported in a study published in 2007 in the *Journal of Clinical Psychopharmacology*.[1] 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.[7] 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

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[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. 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
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)

Methadone is metabolized by several isoforms of the cytochrome P450 (CYP) family, mainly CYP3A4 and CYP2B6, and to a lesser extent by CYP2D6.[1–5] Psychiatric 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.[8] 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,[9] does not display any stereoselective activity toward methadone.[5,10] 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 concentrations[12] (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.

*Centre Psychosocial, Unité de Traitement des Addictions, Fribourg and †Unité de Biochimie et Psychopharmacologie Clinique, Centre des Neurosciences Psychiatriques, Département de Psychiatre—Centre Hospitalier Universitaire Vaudois, Hôpital de Cery, Prilly-Lausanne, Switzerland.

Received August 25, 2006; accepted after revision February 9, 2007.
This work has been supported, in part, by a grant from AstraZeneca.

Address correspondence and reprint requests to Chin B. Eap, PhD, Hôpital de Cery, CH 1008 Prilly-Lausanne, Switzerland. E-mail: Chin.Eap@chuv.ch.

ISSN: 0271-0749/07/2703-0273
DOI: 10.1097/JCP.0b013e3180592ad2

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 activity[16]).

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 chromatography–mass 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-μm 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 NH_4NO_3–1.5% 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*),[2] 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

TABLE 1. (*R*)-Methadone, (*S*)-Methadone, and (*R,S*)-Methadone Concentration-Dose Ratios Before and After the Introduction of Quetiapine (Mean Dosage, 138 mg/d) for a Mean Period of 30 Days

Patient No.	(*R*)-Methadone Before Quetiapine, ng × d/mL × mg	Change of (*R*)-Methadone After Quetiapine, %	(*S*)-Methadone Before Quetiapine, ng × d/mL × mg	Change of (*S*)-Methadone After Quetiapine, %	(*R,S*)-Methadone Before Quetiapine, ng × d/mL × mg	Change of (*R,S*)-Methadone After Quetiapine, %	*CYP2D6* genotype	*ABCB1 3435C>T* Genotype	*CYP2B6* Genotype	Quetiapine Plasma Concentrations, ng/mL
1	1.38	8	1.51	−4	2.89	2	EM	*CT*	**1/*5*	33
3	1.73	85	1.31	107	3.04	95	EM	*CT*	**1/*7*	34
4	1.53	3	1.41	−3	2.94	0	PM	*CC*	**1/*6*	15
5	2.55	42	1.86	115	4.42	73	PM	*CT*	**1/*1*	19
6	1.07	60	0.80	32	1.87	48	IM	*CC*	**1/*1*	13
7	1.93	20	2.37	7	4.30	13	EM	*CT*	**6/*6*	3
8	1.83	−23	2.33	−18	4.17	−20	PM	*CT*	**1/*5*	16
11	1.45	17	0.84	23	2.29	19	IM	*TT*	**1/*5*	19
12	1.57	36	1.53	59	3.10	47	IM	*CC*	**1/*1*	183
13	3.84	2	3.76	5	7.60	3	IM	*TT*	**1/*6*	160
14	3.64	−9	4.48	−30	8.12	−21	IM	*TT*	**1/*6*	108
17	1.18	8	1.22	−4	2.40	2	EM	*CT*	**1/*1*	36
19	1.90	8	2.72	4	4.62	6	IM	*CT*	**6/*6*	31
20	1.13	32	0.99	33	2.11	33	IM	*CT*	**1/*1*	42
Mean	1.91	20.56	1.94	23.37	3.85	21.38	—	—	—	50.89
SD	0.87	28.44	1.10	43.44	1.92	33.83	—	—	—	56.94
P	—	0.026	—	0.12	—	0.064	—	—	—	—

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.

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 activity[22] due to reduced mRNA stability[23]; 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 concentration-dose 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 concentration-dose 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 concentration-dose 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 vivo[11] 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 study[12] (AstraZeneca, data in file) and/or an inhibitory effect toward the PGP transporter system.

With regard to CYP2B6, in vitro[10] and in vivo[2,5] 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 *ABCB1* 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 fluoxetine[8] 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,[7] 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 noticed.

Very recent studies show that methadone can prolong the QT 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.[26] 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.

ACKNOWLEDGMENTS

The authors thank Mrs V. Sari and Mrs K. Powell Golay for editorial assistance and Mrs J. Rosselet, Mrs M. Gobin, and Mrs E. Ponce for bibliographic help.

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

Date:10/16/02ISR Number: 4012516-0Report Type:Periodic Company Report #001-0945-M0200505 Age: Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bradycardia	Health Professional	Neurontin (Gabapentin)	PS				
			Quetiapine	SS				
			Paroxetine Hydrochloride	C				

Date:10/17/02ISR Number: 3995660-3Report Type:Expedited (15-DaCompany Report #2002SE05260 Age:60 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Disseminated Intravascular Coagulation	Foreign Health Professional Other	Seroquel	PS				

Date:10/17/02ISR Number: 3995664-0Report Type:Expedited (15-DaCompany Report #2002AP03042 Age:39 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased	Foreign Health Professional Other	Seroquel	PS		ORAL	150 MG DAILY PO	
	Aspartate Aminotransferase Increased		Seroquel	SS		ORAL	250 MG DAILY PO	
	Blood Alkaline Phosphatase Increased		Solanax	C				
	Gamma-Glutamyltransferase Increased		Sepazon	C				
	Jaundice		Sediel	C				
			Depas	C				
			Isomytal	C				
			Magnesium Oxide	C				
			Amoban	C				
			Yodel	C				
			Paxil	C				
			Tetramide	C				

Date:10/17/02ISR Number: 3995665-2Report Type:Expedited (15-DaCompany Report #2002SE05214 Age:40 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Confusional State	Foreign Health Professional Other	Seroquel	PS		ORAL	300 MG DAILY PO	
	Hyperpyrexia							
	Metabolic Acidosis							
	Renal Failure Acute							
	Respiratory Failure							
	Rhabdomyolysis							

Date:10/17/02ISR Number: 3997318-3Report Type:Expedited (15-DaCompany Report #2002UW13833 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Ineffective	Health Professional	Seroquel	PS		ORAL	200 MG PO	
	Drug Interaction		Methadone	SS				

Date:11/07/02ISR Number: 4009076-7Report Type:Expedited (15-DaCompany Report #2002AP03574 — Age:32 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Propranolol	PS				
	Intentional Overdose	Health	Quetiapine	SS				
		Professional	Alprazolam	SS				

Date:11/07/02ISR Number: 4009158-XReport Type:Expedited (15-DaCompany Report #2002UW14867 — Age:33 YR Gender:Male I/FU:I

Outcome	P	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Angina Pectoris	Health	Seroquel	PS				
	Myocardial Infarction	Professional	Altace	C				
			Lopressor	C				
			Imdur	C				
			Plavix	C				
			Zocor "Dieckmann"	C				

Date:11/07/02ISR Number: 4009253-5Report Type:Expedited (15-DaCompany Report #2002UW14645 — Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death	Consumer	Seroquel	PS				

Date:11/07/02ISR Number: 4009290-0Report Type:Expedited (15-DaCompany Report #2002SE05653 — Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Sudden Death	Foreign	Seroquel	PS				
		Health	Methadone	C				
		Professional	Benzodiazepine	C				
		Other						

Date:11/08/02ISR Number: 4009519-9Report Type:Expedited (15-DaCompany Report #2002SE05579 — Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Herpes Zoster	Foreign	Seroquel	PS		ORAL	600 MG QD PO	
	Leukopenia	Health	Seroquel	SS		ORAL	400 MG QD PO	
	Rash Macular	Professional	Lexotanil	C				
		Other	Akineton	C				
			Stelazine	C				
			Granulokine	C				
			Lithium	C				

Date:11/08/02ISR Number: 4009529-1Report Type:Expedited (15-DaCompany Report #2002SE05604 — Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Neutropenia	Foreign	Seroquel	PS		ORAL	2002 MG QD PO	
		Health						
		Professional						
		Other						

Date:12/16/02ISR Number: 4026990-7Report Type:Expedited (15-DaCompany Report #2000UW00285 Age:21 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bronchopneumonia	Health	Seroquel "Zeneca"	PS	Zeneca			
	Injury	Professional	Methadone	C				
	Pulmonary Congestion		Amitriptyline	C				
	Pulmonary Oedema		Nortriptyline	C				
	Road Traffic Accident		Citalopram	C				
	Toxicologic Test Abnormal							

Date:12/17/02ISR Number: 4028525-1Report Type:Expedited (15-DaCompany Report #APCDSS2002000429 Age:37 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased	Foreign	Risperdal (Tablet) (Risperidone)	PS		ORAL	MG, DAILY, ORAL	
	Blood Pressure Increased	Health	Haldol (Tablet) (Haloperidol)	SS		ORAL	MG, DAILY, ORAL	
	Condition Aggravated	Professional	Quetiapine Fumarate (Quetiapine Fumarate)	SS		ORAL	MG, DAILY, ORAL	
	Decreased Appetite		Hydroxyzine Pamoate (Hydroxyzine)	C				
	Delusion		Estazolam (Estazolam)	C				
	Diabetes Mellitus		Zopiclone (Zopiclone)	C				
	Hallucination		Biperiden Hydrochloride (Biperiden Hydrochloride)	C				
	Hypoventilation							
	Insomnia							
	Respiratory Distress							
	Schizophrenia							

Date:12/17/02ISR Number: 4028692-XReport Type:Expedited (15-DaCompany Report #2002SE05260 Age:58 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Coma	Foreign	Seroquel	PS				
Hospitalization - Initial or Prolonged	Disseminated	Health	Haldol "Janssen"	C				
	Intravascular Coagulation	Professional	Stilnoct	C				
	Drug Toxicity	Other	Trazolan	C				

Date:12/18/02ISR Number: 4025725-1Report Type:Direct Company Report #CTU 183007 Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Movement Disorder		Seroquel 300mg Tabs Astra Zeneca	PS	Astra Zeneca	ORAL	600MG PO QHS	
			Geodon 80mg Caps Pfizer	SS	Pfizer	ORAL	80MG PO BID	
			Altace	C				
			Valproic Acid	C				
			Prevacid	C				
			Klonopin	C				
			Glucophag	C				
			Motrin	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/23/02ISR Number: 4029135-2Report Type:Direct Company Report #CTU 183279 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Somnolence		Quetiapine 50 Mg Bid Po	PS				

Date:12/23/02ISR Number: 4032361-XReport Type:Expedited (15-DaCompany Report #BO287819A Age:38 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Toxicity	Foreign	Paracetamol (Acetaminophen)	PS		ORAL	ORAL	
	Overdose		Quetiapine Fumarate (Quetiapine Fumarate)	SS		ORAL	ORAL	
			Dextropropoxyphene (Dextropropoxyphene)	SS				

Date:12/23/02ISR Number: 4032431-6Report Type:Expedited (15-DaCompany Report #2002UW17056 Age:14 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Liver Function Test Abnormal	Foreign	Seroquel	PS		ORAL	50 MG BID PO	
	Lymphocyte Count Decreased	Health Professional	Wellbutrin	C				
	Mononucleosis Syndrome							
	Neutrophil Count Decreased							
	White Blood Cell Count Decreased							

Date:12/23/02ISR Number: 4033025-9Report Type:Expedited (15-DaCompany Report #2002UW17079 Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Red Blood Cell Count Decreased	Foreign	Seroquel	PS				
		Health	Neurontin	C				
		Professional	Ativan	C				
		Other	Dicetel	C				
			Imovane	C				
			Prevacid	C				
			Clonazepam	C				
			Vitamin B12	C				
			Synthroid	C				

Date:12/23/02ISR Number: 4033027-2Report Type:Expedited (15-DaCompany Report #2002AP043B0 Age:41 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Interaction	Foreign	Seroquel	PS				
	Lethargy	Health	Methadone	SS				
	Malaise	Professional						
		Other						

Date:12/24/02ISR Number: 4033996-0Report Type:Expedited (15-DaCompany Report #2002GB02894

Age:0 DY Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Maternal Drugs Affecting Foetus	Foreign	Seroquel	PS		TRANSPLACENTAL	200 MG BID TPL	
	Talipes	Health Professional Other	Citalopram	SS		TRANSPLACENTAL	40 MG QD TPL	

Date:12/24/02ISR Number: 4033997-2Report Type:Expedited (15-DaCompany Report #2002GB01858

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Induced Labour	Foreign	Seroquel	PS			200 MG BID PO	
	Maternal Drugs Affecting Foetus	Health Professional Other	Cipramil	SS			40 MG QD	
	Pregnancy Induced Hypertension		Ventolin	C				

Date:12/24/02ISR Number: 4033998-4Report Type:Expedited (15-DaCompany Report #2002AP03781

Age:52 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Acute Myocardial Infarction	Foreign	Seroquel	PS			200 MG TID PO	
Required Intervention to Prevent Permanent Impairment/Damage	Cardiomyopathy	Health Professional Other	Olanzapine	SS				
	Delirium		Cipramil	C				
	Psychotic Disorder		Haloperidol	C				
	Ventricular Hypokinesia		Temazepam	C				

Date:12/24/02ISR Number: 4034024-3Report Type:Expedited (15-DaCompany Report #2002AP04371

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Encephalopathy	Foreign	Seroquel	PS				
	Hepatitis Fulminant	Health Professional Other						

Date:12/24/02ISR Number: 4034026-7Report Type:Expedited (15-DaCompany Report #2002AP04390

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsion	Foreign	Seroquel	PS				
	Drug Interaction	Health Professional Other	Methadone	C				

Date:12/24/02ISR Number: 4034027-9Report Type:Expedited (15-DaCompany Report #20025E06175

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Myocardial Infarction	Foreign	Seroquel	PS		ORAL	350 MG QD PO	
		Health Professional Other	Stedon	C				
			Dipiperon	C				
			Aloperidin	C				
			Zyprexa	C				

White Blood Cell Count
Decreased

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Foreign	Seroquel	PS		ORAL	50 MG BID PO	
Health	Wellbutrin	C				
Professional						
Other						

Date:12/27/02ISR Number: 4034463-0Report Type:Expedited (15-DaCompany Report #2002SE06067 Age:22 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Menstruation Irregular	Foreign	Seroquel	PS		ORAL	600 MG QD PO	
	Thrombocytopenia	Health	Xanax	C				
		Professional						
		Other						

Date:12/27/02ISR Number: 4034466-6Report Type:Expedited (15-DaCompany Report #2002SE06332 Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Leukopenia	Foreign	Seroquel	PS		ORAL	100 MG QID PO	
	Neutropenia	Health	Serenase	C				
		Professional	Temesta	C				
		Other	Thyroxin	C				
			Burana	C				

Date:12/27/02ISR Number: 4034747-6Report Type:Expedited (15-DaCompany Report #2002071920 Age:45 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Anger	Foreign	Zoloft (Sertraline)	PS		ORAL	20 MG (DAILY), ORAL	
	Drug Abuser	Health						
	Parkinson'S Disease	Professional	Quetiapine	SS		ORAL	ORAL	
			Methadone	SS		ORAL	70 MG (DAILY), ORAL	
			Chlorpromazine	C				
			Clotiapine	C				
			Delorazepam	C				
			Flurazepam	C				

Date:12/27/02ISR Number: 4034993-1Report Type:Expedited (15-DaCompany Report #2002GB02891 Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Withdrawal Syndrome	Foreign	Quetiapine	PS		TOPICAL	400 MG BID TPL	
Required Intervention to Prevent Permanent Impairment/Damage	Neonatal	Health						
	Hypervigilance	Professional	Paroxetine	SS		TOPICAL	20 MG QD TPL	
	Hypotonia Neonatal	Other	Pethidine	C				
	Induced Labour							
	Insomnia							
	Maternal Drugs Affecting Foetus							
	Neonatal Disorder							

Initial or Prolonged

PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Aggression	Foreign	Aldactone(Spironolac					
Agranulocytosis	Health	tone) Tablet	PS		ORAL	50 MG, DAILY,	
Angina Pectoris	Professional					ORAL	
C-Reactive Protein	Other	Seroquel(Quetiapine)	SS		ORAL	ORAL	
Increased		Torem(Torasemide)	SS		ORAL	10 MG DAILY,	
Cough						ORAL	
Depression		Marcoumar					
Disorientation		(Phenprocoumon)	C				
Dizziness		Beloc Zok					
Dyspnoea		(Metoprolol					
Lung Infection		Succinate)	C				
Neutropenia							
Pyrexia							
Restlessness							
Rhonchi							
Sputum Discoloured							
Vascular Dementia							
Wheezing							

Date:07/29/03ISR Number: 4157512-8Report Type:Direct Company Report #CTU 198893 Age:34 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Mental Retardation		Seroquel	PS				
	Road Traffic Accident		Lithium	SS				

Date:07/29/03ISR Number: 4159248-6Report Type:Expedited (15-DaCompany Report #2003GB02021 Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Electrocardiogram	Foreign	Seroquel	PS				
	Abnormal	Health	Seroxat	C	Ciba-Geigy			
	Leukopenia	Professional						
		Other						

Date:07/29/03ISR Number: 4159249-8Report Type:Expedited (15-DaCompany Report #2003GB01547 Age:29 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Hypersensitivity	Foreign	Seroquel	PS		ORAL	50 MG ONCE PO	
Required		Health	Sertraline	C				
Intervention to		Professional	Depakote	C				
Prevent Permanent		Other	Chlorpromazine	C				
Impairment/Damage								

Date:07/29/03ISR Number: 4159627-7Report Type:Expedited (15-DaCompany Report #2003UW09220 Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Interaction	Health	Seroquel	PS				
	Sedation	Professional	Methadone	SS				

Date:08/27/03ISR Number: 4180638-XReport Type:Expedited (15-DaCompany Report #2003UW10563 Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Toxicity	Health Professional	Seroquel	PS		ORAL	800 MG DAILY PO	
	Hepatic Cirrhosis							
	Pulmonary Congestion		Methadone	C				
	Pulmonary Oedema		Zoloft	C				

Date:08/27/03ISR Number: 4181188-7Report Type:Expedited (15-DaCompany Report #M0929-03 Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Chest Pain		Mirtazapine	PS		ORAL	60 MG ORAL	
	Drug Interaction		Seroquel	SS		ORAL	300 MG ORAL	
	Hypotension		Atropine Sulfate	SS		PARENTERAL	0.5 MG PARENTERAL	1 DAY
	Supraventricular Tachycardia		Oxazepam	C				

Date:08/28/03ISR Number: 4175080-1Report Type:Periodic Company Report #US-BRISTOL-MYERS SQUIBB COMPANY-12246666 Age:41 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Glucose Increased		Abilify Tabs 10 Mg	PS	Otsuka Pharmaceutical Company, Ltd.	ORAL		4 DAY
Other	Diabetes Mellitus		Seroquel	SS				
			Valproic Acid	C				
			Haldol	C				

Date:08/28/03ISR Number: 4175192-2Report Type:Periodic Company Report #US-BRISTOL-MYERS SQUIBB COMPANY-12291316 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Agitation		Abilify Tabs	PS	Otsuka Pharmaceutical Company, Ltd.			
	Drug Interaction							
	Hallucination		Seroquel	I				

Date:08/29/03ISR Number: 4175730-XReport Type:Expedited (15-DaCompany Report #GB-BRISTOL-MYERS SQUIBB COMPANY-12363263 Age:59 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Neuroleptic Malignant Syndrome		Sinemet Cr Tabs	PS	Bristol-Myers Squibb Company	ORAL	"at bedtime"	
Hospitalization - Initial or Prolonged	Renal Failure		Carbidopa + Levodopa Tabs	SS	Bristol-Myers Squibb Company	ORAL	narrative stated "20, once a day" and daily dose block on	
			Quetiapine Fumarate	SS				

Hypertonia Neonatal Maternal Drugs Affecting Foetus Nasal Flaring Neonatal Disorder Neonatal Respiratory Distress Syndrome Oxygen Saturation Decreased Respiratory Disorder Neonatal Respiratory Rate Increased Weight Decreased Weight Gain Poor	Report Source Foreign Health Professional Other	Product Seroquel Lorazepam	Role Manufacturer PS SS	Route TRANSPLACENTAL TRANSPLACENTAL	Dose 150 MG QTD TPL 2 MG TID TPL	Duration

Date:09/25/03ISR Number: 4200659-8Report Type:Expedited (15-DaCompany Report #JP-JNJFOC-20030904254 Age:67 YR Gender:Male I/FU:I

Outcome Hospitalization - Initial or Prolonged	PT Face Oedema Insomnia Oedema Sluggishness Stevens-Johnson Syndrome	Report Source Foreign Health Professional	Product Risperidone (Risperidone) Unspecified Quetiapine (Quetiapine) Unknown	Role Manufacturer PS SS	Route ORAL ORAL	Dose 2 MG IN 1 DAY ORAL 2 MG IN 1 DAY ORAL	Duration

Date:09/25/03ISR Number: 4200713-0Report Type:Expedited (15-DaCompany Report #2003UW10563 Age:47 YR Gender:Female I/FU:F

Outcome Death	PT Drug Toxicity Hepatic Cirrhosis Medication Error Pulmonary Congestion Pulmonary Oedema	Report Source Health Professional	Product Seroquel Methadone Zoloft	Role Manufacturer PS C C	Route ORAL	Dose 400 MG DAILY PO	Duration

Date:09/25/03ISR Number: 4200922-0Report Type:Expedited (15-DaCompany Report #2003GB02388 Age: Gender:Male I/FU:I

Outcome Other	PT Thrombocytopenia	Report Source Foreign Health Professional Other	Product Seroquel Digoxin Warfarin Atenolol	Role Manufacturer PS C C C	Route	Dose PT ON SEROQUEL FOR 2-3 WEEKS	Duration

Date:09/26/03ISR Number: 4197110-3Report Type:Direct Company Report #CTU 202721 Age:27 YR Gender:Male I/FU:I

Outcome
Life-Threatening
Required
Intervention to
Prevent Permanent

Date:09/26/03ISR Number: 4210381-XReport Type:Periodic Company Report #2003UW04343 Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Electrocardiogram Qt Prolonged	Health Professional	Seroquel	PS		ORAL	100 MG DAILY PO	
			Methadone	C				

Date:09/26/03ISR Number: 4210382-1Report Type:Periodic Company Report #2003UW04380 Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Urinary Retention	Health Professional	Seroquel	PS		ORAL	300 MG DAILY PO	

Date:09/26/03ISR Number: 4210383-3Report Type:Periodic Company Report #2003UW04615 Age:32 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Angle Closure Glaucoma	Consumer	Seroquel	PS		ORAL	100 MG DAILY PO	
	Blood Cholesterol Increased		Seroquel	SS		ORAL	200 MG DAILY PO	
	Blood Triglycerides Increased		Celexa	C				
	Body Temperature Increased		Risperdal	C				
	Eye Pain		Lexapro	C				
	Ocular Hyperaemia		Desyrel	C				
	Vision Blurred		Trileptal	C				
	Weight Increased							

Date:09/26/03ISR Number: 4210384-5Report Type:Periodic Company Report #2003UW04581 Age:25 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Grand Mal Convulsion	Health Professional	Seroquel	PS		ORAL	1000 MG PO	
			Seroquel	SS		ORAL	1000 MG PO	
			Geodon	C				
			Risperdal	C				
			Clonidine	C				
			Depakote	C				
			Zyprexa	C				
			Prolixin	C				
			Klonopin	C				

Date:09/26/03ISR Number: 4210385-7Report Type:Periodic Company Report #2003UW05072 Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Cataract	Health Professional	Seroquel	PS		ORAL	600 MG DAILY PO	
			Paxil	C				
			Buspar	C				
			Trilafon	C				
			Amantadine	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/03/03ISR Number: 4226096-8Report Type:Expedited (15-DaCompany Report #2003UW13821 — Age: — Gender:Female — I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Sleep Apnoea Syndrome	Health Professional	Seroquel	PS		ORAL	1200 MG QD PO	

Date:11/03/03ISR Number: 4226098-1Report Type:Expedited (15-DaCompany Report #2003UW13607 — Age:58 YR — Gender:Female — I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Anxiety Balance Disorder Ill-Defined Disorder Medication Error Memory Impairment Muscle Spasms Muscle Twitching Paranoia	Consumer	Seroquel Serzone Paxil	PS SS C		ORAL	600 MG ONCE PO	

Date:11/03/03ISR Number: 4226124-XReport Type:Expedited (15-DaCompany Report #2003UW13923 — Age: — Gender: — I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Drug Withdrawal Syndrome Feeling Jittery Hypertonia Neonatal Maternal Drugs Affecting Foetus Neonatal Disorder	Health Professional	Seroquel	PS				

Date:11/03/03ISR Number: 4226629-1Report Type:Expedited (15-DaCompany Report #2003GB02744 — Age:55 YR — Gender:Male — I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Myocardial Infarction Neuroleptic Malignant Syndrome Pneumonia Aspiration Pulmonary Embolism	Foreign Health Professional Other	Seroquel Carbamazepine Losec Akineton	PS C C C		ORAL	300 MG BID PO	

Date:11/03/03ISR Number: 4226854-XReport Type:Expedited (15-DaCompany Report #2003UW13857 — Age:77 YR — Gender:Female — I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Drug Effect Decreased Epistaxis Platelet Count Decreased	Foreign Health Professional Other	Seroquel Calcium Tylenol Isopto Olanzapine	PS C C C C				

Date:11/03/03ISR Number: 4226882-4Report Type:Expedited (15-DaCompany Report #2003-DE-05125GD — Age:39 YR — Gender: — I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Multiple Drug Overdose	Literature	Methadone (Methadone)	PS		ORAL	PO	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:12/29/03ISR Number: 4261245-7Report Type:Expedited (15-DaCompany Report #2003PK02143 Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Arrhythmia	Foreign	Seroquel "Zeneca"	PS		ORAL	300 MG DAILY PO	
	Blood Sodium Decreased	Study	Seroquel Zeneca	SS		ORAL	300 MG DAILY PO	
	Circulatory Collapse	Health Professional	Diuretic	SS				
	Eye Disorder	Other	Euphylong	C				
	Hypokalaemia		Karvezide	C				
			L-Thyroxin	C				
			Melperon					
			Ct-Arzneimittel	C				
			Noveril	C				
			Mirtazepin	C				
			Temazepam	C				

Date:12/29/03ISR Number: 4261489-4Report Type:Expedited (15-DaCompany Report #2003120450 Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Acute Psychosis	Health Professional	Neurontin (Gabapentin)	PS		ORAL	900 MG (TID), ORAL	
Other	Catatonia		Quetiapine Fumarate (Quetiapine Fumarate)	SS		ORAL	ORAL	
	Electroencephalogram Abnormal		Zoloft (Sertraline)	C				
	Hallucinations, Mixed		Nortriptyline (Nortriptyline)	C				
			Carbamazepine (Carbamazepine)	C				
			Morphine Sulfate (Morphine Sulfate)	C				
			Oestranorm (Estradiol, Norethisterone)	C				
			Levothyroxine Sodium (Levothyroxine Sodium)	C				
			Clonazepam (Clonazepam)	C				

Date:12/29/03ISR Number: 4261670-4Report Type:Direct Company Report #CTU 208905 Age:18 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Leukopenia		Quietapine	PS		ORAL	P.O. 350 MG/DAY	
	Neutropenia		Effexor Xr	C				

Date:12/29/03ISR Number: 4261718-7Report Type:Expedited (15-DaCompany Report #2003UW16557 Age:33 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Toxicity	Health Professional	Seroquel	PS		ORAL	800 MG QD PO	5 MON
	Multiple Drug Overdose		Seroquel	SS		ORAL	1000 MG QD PO	

Professional
Other

Product	Role	Manufacturer	Route	Dose	Duration
Seroquel	PS		ORAL	50 MG DAILY PO	
Diltizem	C				
Surgam	C				
Madopar	C				

Date:04/01/04ISR Number: 4332497-XReport Type:Expedited (15-DaCompany Report #2003AP03972 Age:77 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Blood Creatine Phosphokinase Increased	Foreign	Seroquel	PS		ORAL	100 MG DAILY PO	
	Fracture	Health Professional	Cravit	C				
	Pyrexia	Other	Telesmin	C				
	Thrombocytopenia		Risperdal	C				
			Gramalil	C				

Date:04/01/04ISR Number: 4333217-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20040202825 Age:80 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aortic Valve Incompetence	Study	Risperidone (Risperidone)	PS		ORAL	ORAL	
	Blood Creatine Phosphokinase Mb Increased	Health Professional	Olanzapine (Olanzapine)	SS		ORAL	ORAL	
	Cerebral Atrophy		Quetiapine (Quetiapine)	SS		ORAL	ORAL	
	Electrocardiogram Q Waves		Ziprasidone (Ziprasidone)	SS		ORAL	ORAL	
	Fall		Perphenazine (Perphenazine)	SS		ORAL	ORAL	
	Hypertension		Lorazepam (Lorazepam)	C				
	Mobility Decreased							
	Myoglobin Blood Increased							
	Proteinuria							
	Qrs Axis Abnormal							
	Ventricular Extrasystoles							

Date:04/01/04ISR Number: 4333234-5Report Type:Expedited (15-DaCompany Report #2004UW05863 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Loss Of Consciousness	Health Professional	Seroquel	PS				
	Medication Error							
	Overdose							

Date:04/01/04ISR Number: 4333240-0Report Type:Expedited (15-DaCompany Report #2004UW05900 Age:50 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Depression	Consumer	Seroquel	PS		ORAL	500 MG DAILY PO	
Required Intervention to Prevent Permanent Impairment/Damage	Medication Error		Serzone	SS		ORAL	500 MG DAILY PO	7 YR
	Panic Attack		Neurontin	C				
	Suicidal Ideation		Skelaxin	C				

Nicotine (Nicotine)	SS	
Lidocaine (Lidocaine)	SS	

Date:06/21/04ISR Number: 4414570-0Report Type:Periodic Company Report #USA-2003-0012008 Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose	Health	Oxycontin Tablets (Oxycodone Hydrochloride)	PS				
Other	Drug Dependence	Professional	Methadone (Methadone)	SS				
	Multiple Drug Overdose	Other	Alprazlam (Alprazolam)	SS				
			Quetiapine (Quetiapine)	SS				

Date:06/22/04ISR Number: 4385380-8Report Type:Expedited (15-DaCompany Report #2004UW12511 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Blood Creatine Phosphokinase Increased	Health Professional	Seroquel	PS				
	Drug Interaction		Lithium	SS				

Date:06/22/04ISR Number: 4385382-1Report Type:Expedited (15-DaCompany Report #2004UW12540 Age:24 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	White Blood Cell Count Decreased	Health Professional	Seroquel	PS		ORAL	500 MG QD PO	
			Zyprexa	C				

Date:06/22/04ISR Number: 4385383-3Report Type:Expedited (15-DaCompany Report #2004UW12369 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bradycardia	Health Professional	Seroquel	PS		ORAL	200 MG PO; 100 MG PO	
	Cardiac Arrest		Lamictal	C				

Date:06/22/04ISR Number: 4385384-5Report Type:Expedited (15-DaCompany Report #2004UW12429 Age:76 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaemia	Health Professional	Seroquel	PS				

Date:06/22/04ISR Number: 4385398-5Report Type:Expedited (15-DaCompany Report #2004UW09918 Age:47 YR Gender:Not SpecifiI/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Health Professional	Seroquel	PS		ORAL	13800 MG ONCE PO	
	Overdose							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/17/04ISR Number: 4504434-6Report Type:Direct — Company Report #CTU 232346 — Age: — Gender:Male — I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour		Seroquel 100 Mg	PS		ORAL	100 MG PO BID	6 MON
	Communication Disorder		Risperdal 2 Mg	SS		ORAL	2 MG PO QHS	6 MON
	Neuroleptic Malignant Syndrome		Zoloft	C				
			Valproic Acid	C				

Date:11/17/04ISR Number: 4504471-1Report Type:Direct — Company Report #CTU 232322 — Age:57 YR — Gender:Male — I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypotension		Seroquel 100mg Tablet	PS		ORAL	100MG HS, BY MOUTH	
	Mental Status Changes		Prednisone Tab	C				
			Chlordiazepoxide Cap	C				
			Nicotine Transdermal Patch	C				
			Insulin, Human Reg, Novolin-R	C				
			Oxycodone/Acetaminophen	C				
			Trazodone Hcl (Desyrel) Tab	C				
			Sertraline Hcl (Zoloft) Tab	C				
			Gabapentin Cap	C				
			Simvastatin (Zocor) Tab	C				
			Lisinopril Tab	C				
			Omeprazole (Prilosec For Inpatient Use) Cap, Sa	C				
			Thiamine Hcl Tab	C				
			Folic Acid Tab	C				
			Metoprolol Tartrate Tab	C				
			Diazepam Inj	C				
			Clopidogrel Bisulfate Tab	C				
			Aspirin Tab	C				

Date:11/17/04ISR Number: 4505145-3Report Type:Direct — Company Report #CTU 232218 — Age:58 YR — Gender:Male — I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State		Quetinpine	PS			400 ML QHS	
			Methadone	SS			5 ML Q 8 H	
			Lorazepam	SS			0.5 ML BID 1M Q HS	
			Asa	C				
			Plavix	C				
			Lopid	C				
			Lisinopril	C				
			Metoprolol	C				
			Naproxen	C				

Olanzapine (Olanzapine)	C

Date:03/14/05ISR Number: 4609619-6Report Type:Direct Company Report #CTU 243102 Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Depressed Level Of Consciousness Oxygen Saturation Decreased		Quetiapine Methadone Hydrochloride	PS C			100 MG	

Date:03/14/05ISR Number: 4609761-XReport Type:Expedited (15-DaCompany Report #2005-DE-00776GD Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Pancytopenia	Literature	Diclofenac (Diclofenac) (Nr) (Diclofenac Sodium) Quetiapine (Quetiapine) (Nr)	PS SS				

Date:03/15/05ISR Number: 4608485-2Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0549462A Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction Ill-Defined Disorder		Wellbutrin Sr	PS	Glaxosmithkline	ORAL		
			Lithium	SS	Glaxosmithkline			
			Cogentin	SS				
			Klonopin	SS				
			Trazodone	SS				
			Prolixin	SS				
			Seroquel	SS				

Date:03/15/05ISR Number: 4608486-4Report Type:Expedited (15-DaCompany Report #US-GLAXOSMITHKLINE-A0549464A Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction		Wellbutrin Sr	PS	Glaxosmithkline	ORAL		
			Cogentin	SS				
			Trazodone	SS				
			Seroquel	SS				
			Klonopin	SS				
			Trilafon	SS	Glaxosmithkline			

Date:03/15/05ISR Number: 4608612-7Report Type:Expedited (15-DaCompany Report #PHBS2004JP17256 Age:72 YR Gender:Female I/FU:F

Outcome	PT
Other	Anaemia Blood Alkaline Phosphatase Increased Haemoglobin Decreased Malaise Pancytopenia Platelet Count Decreased

			Pharmaceuticals	ORAL
	Loxonin	SS		ORAL
	Mobic	SS		ORAL

Date:05/24/05ISR Number: 4695588-XReport Type:Expedited (15-DaCompany Report #2005PK00839 Age:230 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Myopia		Seroquel	PS	Zeneca Pharmaceutical	ORAL		

Date:05/24/05ISR Number: 4695590-8Report Type:Expedited (15-DaCompany Report #2005UW06382 Age:25304 DYGender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Bilirubin Increased		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
Disability	Hepatic Function Abnormal							
	Jaundice							

Date:05/24/05ISR Number: 4695592-1Report Type:Expedited (15-DaCompany Report #2005UW07520 Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Aphasia		Seroquel	PS	Zeneca Pharmaceutical	ORAL		5 MON
	Blood Glucose Increased		Duragesic	C				
	Dystonia		Percocet	C				
	Thinking Abnormal		Somazapam	C				
	Visual Acuity Reduced		Robaxin	C				
			Ranitidine	C				
			Lithium	C				
			Amitriptyline	C				
			Bentyl	C				
			Glucosamine	C				
			Isoflavins	C				

Date:05/24/05ISR Number: 4695593-3Report Type:Expedited (15-DaCompany Report #2005UW07559 Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Abuser		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
	Intentional Drug Misuse		Seroquel	SS	Zeneca Pharmaceutical	ORAL		
	Loss Of Consciousness		Methadone	C				
	Overdose		Xanax	C				
	Self-Injurious Ideation		Crack	C				
	Weight Decreased		All Kinds Of Drugs	C				

Date:05/24/05ISR Number: 4695595-7Report Type:Expedited (15-DaCompany Report #2005UW07673 Age:9 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Disability	Blindness		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
Other	Deafness		Zoloft	C				
			Propanolol	C				

Date:08/03/05ISR Number: 4738261-1Report Type:Expedited (15-DaCompany Report #HQWYE240122MAR05 Age:53 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation Amenorrhoea Blood Cholesterol Increased Bruxism Candidiasis Condition Aggravated Dermatitis Exfoliative Drug Dependence Drug Withdrawal Syndrome Flushing Gallbladder Operation Hypomania Memory Impairment Menopause Poor Peripheral Circulation Psoriasis Skin Discolouration Skin Exfoliation Skin Haemorrhage Suicidal Ideation Tongue Biting Tooth Disorder	Consumer	Efexor Xr (Venlafaxine Hydrochloride, Capsule, Extended Release)	PS		ORAL	150 MG 1X PER 1 DAY ORAL; 75 MG1X PER 1 DAY ORAL	1 WK
			Efexor (Venlafaxine Hydrochloride, Tablet)	SS		ORAL	37.5 MG 1X PER 1 DAY ORAL	2 WK
			Seroquel (Quetiapine)	SS		ORAL	100 MG 1X PER 1 DAY ORAL	
			Neurontin (Gabapentin)	C				
			Valium (Diazepam)	C				
			Xanax (Alprazolam)	C				
			Pariet (Rabeprazole)	C				
			Renitec (Enalapril Maleate)	C				
			Di-Gesic (Dextropropoxyphene/ Paracetamol)	C				
			Pethidine (Pethidine)	C				
			Vitamins (Vitamins)	C				

Date:08/04/05ISR Number: 4734125-8Report Type:Expedited (15-DaCompany Report #2005UW11176 Age:53 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypotension Loss Of Consciousness		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
			Methadone	C				
			Unspecified Ssri	C				
			Lithobid	C				
			Klonopin	C				

Date:08/04/05ISR Number: 4734602-XReport Type:Expedited (15-DaCompany Report #2005UW11346 Age:1 DY Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Cyanosis Neonatal Drug Exposure During Pregnancy Premature Baby		Seroquel	PS	Zeneca Pharmaceutical	ORAL		186 DAY

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:09/26/05ISR Number: 4778870-7Report Type:Expe ited (15-DaCompany Report #2005UW13844 Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Haemoglobin Decreased		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
	Mean Cell Volume Decreased		Aspirin	C				
	Proctalgia							
	Pyrexia							
	Rash Generalised							
	Red Blood Cell Count Increased							
	Vulvovaginal Pain							

Date:09/26/05ISR Number: 4779031-8Report Type:Expedited (15-DaCompany Report #US-ABBOTT-03P-163-0228662-00 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Condition Aggravated		Depakote	PS				1 WK
	Dermatitis Bullous		Risperidone	SS				
	Erythema Multiforme		Risperidone	SS				
	Fall		Quetiapine	SS				
	Joint Stiffness		Quetiapine	SS				
	Neuroleptic Malignant Syndrome							

Date:09/26/05ISR Number: 4780288-8Report Type:Expedited (15-DaCompany Report #2005128538 Age:42 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Literature	Alprazolam (Alprazolam)	PS				
	Completed Suicide	Health Professional	Methadone (Methadone)	SS				
	Drug Toxicity		Quetiapine (Quetiapine)	SS				
	Intentional Drug Misuse		All Other Therapeutic Products (All Other Therapeutic Products)	SS				
	Overdose							
	Respiratory Arrest							

Date:09/26/05ISR Number: 4780436-XReport Type:Expedited (15-DaCompany Report #2005127472 Age:76 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Literature	Amlodipine (Amlodipine)	PS		ORAL	ORAL	
	Completed Suicide	Health Professional	Quetiapine (Quetiapine)	SS		ORAL	ORAL	
	Drug Toxicity							
	Intentional Drug Misuse							
	Multiple Drug Overdose							

Date:09/26/05ISR Number: 4780437-1Report Type:Expedited (15-DaCompany Report #2005127620 Age: Gender:Unknown I/FU:I

Outcome	PT
Death	Cardio-Respiratory Arrest
	Completed Suicide

Date:10/04/05ISR Number: 4787052-4Report Type:Expedited (15-DaCompany Report #RO-JNJFOC-20050900860

Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Urticaria		Quetiapine	PS		ORAL		28 DAY
			Seroquel	SS		ORAL		28 DAY

Date:10/04/05ISR Number: 4787063-9Report Type:Expedited (15-DaCompany Report #2005UW14398

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Autonomic Nervous System Imbalance		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
	Confusional State		Methadone Maintenance	C				
	Hyperhidrosis							
	Hypotension							
	Metabolic Acidosis							
	Pneumonia							
	Renal Failure Acute							

Date:10/04/05ISR Number: 4787065-2Report Type:Expedited (15-DaCompany Report #2005SE05479

Age:29420 DYGender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cerebrovascular Accident		Seroquel	PS	Zeneca Pharmaceutical	ORAL	25 MG THREE TIMES A DAY	62 DAY
			Lanoxin	C		ORAL	0.125 MG DAILY	
			Lasix (Furosemide)	C			25 MG	

Date:10/04/05ISR Number: 4787071-8Report Type:Expedited (15-DaCompany Report #2005AC01292

Age:488 MON Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bulimia Nervosa		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
			Depakine	C		ORAL		
			Maniprex	C		ORAL		
			Seroxat	C		ORAL		

Date:10/04/05ISR Number: 4788231-2Report Type:Direct Company Report #CTU 259464

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Migraine		Seroquel 25mg Astra Zeneca	PS	Astra Zeneca	ORAL	25MG ONCE DAILY PO	

Date:10/04/05ISR Number: 4789051-5Report Type:Expedited (15-DaCompany Report #DSA_27143_2005

Age:32 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Multiple Drug Overdose	Literature	Lorazepam	PS		ORAL	DF UNK PO	
		Health Professional	Quetiapine	SS		ORAL	DF UNK PO	
			Acetaminophen Pm	SS		ORAL	DF UNK PO	

Feeling Jittery Gait Disturbance Headache Syncope Tremor	Report Source	Product Quetiapine 100 Mg Lamotrigine Fluoxetine Clonazepam Apap	Role Manufacturer PS C C C C	Route ORAL	Dose 100 MG PO	Duration	

Date:10/05/05ISR Number: 4790056-9Report Type:Direct Company Report #CTU 259787 Age: Gender:Female I/FU:I

Outcome Required Intervention to Prevent Permanent Impairment/Damage	PT Drug Clearance Decreased Drug Level Increased Hypothermia	Report Source	Product Biaxin 500mg Seroquel 100mg Daily Accuchecks Prevpak -Amox Biaxin Prevacid Doxycycline Fosamax Levaquin Levothyroxine One-Tab Daily Vitamins Seroquel Zoloft	Role Manufacturer PS SS C C C C C C C C C C C	Route ORAL ORAL	Dose 500MG BID PO 250MG TID PO	Duration 14 DAY

Date:10/05/05ISR Number: 4790135-6Report Type:Direct Company Report #CTU 259695 Age: Gender:Male I/FU:I

Outcome Hospitalization - Initial or Prolonged	PT Agitation Hypotension Overdose Somnolence Tachycardia	Report Source	Product Seroquel	Role Manufacturer PS	Route	Dose	Duration

Date:10/05/05ISR Number: 4790676-1Report Type:Expedited (15-DaCompany Report #DSA_70812_2005 Age:43 YR Gender: I/FU:I

Outcome Death	PT Completed Suicide Multiple Drug Overdose	Report Source Literature Health Professional	Product Methadone Quetiapine Citalopram	Role Manufacturer PS SS SS	Route ORAL ORAL ORAL	Dose DF PO DF PO DF PO	Duration

Date:10/05/05ISR Number: 4791975-XReport Type:Expedited (15-DaCompany Report #DSA_70811_2005 Age:42 YR Gender: I/FU:I

Outcome Death	PT Cardio-Respiratory Arrest Completed Suicide Multiple Drug Overdose	Report Source Literature Health Professional	Product Methadone Quetiapine Alprazolam	Role Manufacturer PS SS SS	Route ORAL ORAL ORAL	Dose DF UNK PO DF UNK PO DF UNK PO	Duration

Date:10/05/05ISR Number: 4793351-2Report Type:Expedited (15-DaCompany Report #DSA_70816_2005 Age:46 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Literature	Methadone	PS		ORAL	DF, PO	
	Multiple Drug Overdose	Health	Zolpidem	SS		ORAL	PO	
		Professional	Quetiapine	SS		ORAL	DF PO	

Date:10/06/05ISR Number: 4789478-1Report Type:Expedited (15-DaCompany Report #2005UW14771 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Overdose		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
	Suicidal Ideation							

Date:10/06/05ISR Number: 4789564-6Report Type:Expedited (15-DaCompany Report #2005UW14702 Age:667 MON Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	White Blood Cell Count Decreased		Seroquel	PS	Zeneca Pharmaceutical	ORAL		

Date:10/06/05ISR Number: 4789667-6Report Type:Expedited (15-DaCompany Report #2005AP02307 Age:12736 DYGender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Intentional Self-Injury		Quetiapine	PS	Zeneca Pharmaceutical	ORAL		4 MON
	Libido Increased		Quetiapine	SS	Zeneca Pharmaceutical	ORAL		
			Lorazepam	C		ORAL	AS REQUIRED	
			Moclobemide	C		ORAL	AT NIGHT	
			Moclobemide	C		ORAL	2 TABLETS	
			Temazepam	C		ORAL	1 - 2 TABLETS	
			Multivite Six	C			ONE TABLET	
			Pamol	C			3-4 TIMES	
			Propranolol	C			DAILY	

Date:10/06/05ISR Number: 4789675-5Report Type:Expedited (15-DaCompany Report #2005SE05495 Age:12356 DYGender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Schizophrenia		Quetiapine	PS	Zeneca Pharmaceutical	ORAL		
			Quetiapine	SS	Zeneca Pharmaceutical	ORAL		

Date:10/06/05ISR Number: 4789827-4Report Type:Expedited (15-DaCompany Report #2005018344 Age:45 YR Gender:Female I/FU:F

Outcome	PT
Hospitalization - Initial or Prolonged	Alcohol Use
	Electrocardiogram Qt Prolonged

Date:10/06/05ISR Number: 4792026-3Report Type:Expedited (15-DaCompany Report #PAR_0219_2005 Age:43 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Citalopram	PS		ORAL	DF UNK PO	
	Multiple Drug Overdose	Health	Methadone	SS		ORAL	DF UNK PO	
		Professional	Quetiapine	SS		ORAL	DF UNK PO	

Date:10/06/05ISR Number: 4792029-9Report Type:Expedited (15-DaCompany Report #PAR_0311_2005 Age:37 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Propranolol	PS		ORAL	DF UNK PO	
	Intentional Drug Misuse	Health	Acetaminophen					
	Multiple Drug Overdose	Professional	W/Propoxyphene	SS		ORAL	DF UNK PO	
			Quetiapine	SS		ORAL	DF UNK PO	

Date:10/06/05ISR Number: 4792036-6Report Type:Expedited (15-DaCompany Report #PAR_0223_2005 Age:19 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Multiple Drug Overdose	Literature	Citalopram	PS		ORAL	DF UNK PO	
		Health	Phenobarbital	SS		ORAL	DF UNK PO	
		Professional	Quetiapine	SS		ORAL	DFUNK PO	

Date:10/06/05ISR Number: 4793451-7Report Type:Expedited (15-DaCompany Report #AND_0188_2005 Age:73 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Acetaminophen					
	Multiple Drug Overdose	Health	W/Propoxyphene	PS			DF	
		Professional	Quetiapine	SS			DF	
			Unknown Chemical	SS			DF	

Date:10/06/05ISR Number: 4793522-5Report Type:Expedited (15-DaCompany Report #PAR_0270_2005 Age:22 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Fluoxetine	PS		ORAL	DF PO	
	Multiple Drug Overdose	Health	Quetiapine	SS		ORAL	DF PO	
		Professional	Methanol	SS		ORAL	DF PO	

Date:10/06/05ISR Number: 4793543-2Report Type:Expedited (15-DaCompany Report #AND_0080_2005 Age:37 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Acetaminophen					
	Multiple Drug Overdose	Health	W/Propoxyphene	PS			DF	
		Professional	Propranolol	SS			DF	
			Quetiapine	SS			DF	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/12/05ISR Number: 4799980-4Report Type:Direct Company Report #CTU 260490 Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blepharospasm Cerebrovascular Accident Facial Palsy Hypoaesthesia Oral Overdose Suicide Attempt Treatment Noncompliance		Seroquel -Quetiapine- Astrazeneca	PS	Astrazeneca	ORAL	100MG BID PO	

Date:10/12/05ISR Number: 4800344-5Report Type:Expedited (15-DaCompany Report #2005-BP-12458RO Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Ammonia Increased Blood Bilirubin Increased Mental Status Changes	Health Professional	Methadone Hcl Tablets Usp, 10 Mg (Methadone Hydrochloride)	PS		ORAL	5 MG BID (5 MG), PO 1 TO 2 WEEKS	
			Seroquel (Quetiapine Fumarate)	SS		ORAL	125 MG QHS PO 1 TO 2 WEEKS	
			Lexapro (Escitalopram Oxalate)	SS		ORAL	10 MG/DAY PO 1 TO 2 WEEKS	
			Xeloda (Capecitabine)	C				

Date:10/12/05ISR Number: 4801236-8Report Type:Expedited (15-DaCompany Report #2005138035 Age:54 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Pressure Decreased Bradycardia Intentional Drug Misuse Overdose	Foreign Health Professional	Nardil (Phenelzine Sulfate)	PS		ORAL	800 MG, ORAL	
			Atenolol (Atenolol)	SS		ORAL	ORAL	
			Seroquel (Quetiapine Fumarate)	SS		ORAL	75 MG, ORAL	

Date:10/13/05ISR Number: 4796877-0Report Type:Expedited (15-DaCompany Report #2005SE04172 Age:8874 DY Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Schizophrenia		Quetiapine	PS	Zeneca Pharmaceutical	ORAL		178 DAY

Date:10/13/05ISR Number: 4797325-7Report Type:Expedited (15-DaCompany Report #2005UW14478 Age:64 YR Gender:Male I/FU:F

Outcome	PT
Life-Threatening Other	Dystonia Neuroleptic Malignant Syndrome Oculogyric Crisis

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/14/05ISR Number: 4827267-XReport Type:Expedited (15-DaCompany Report #2005AC01745 Age:8 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Accidental Overdose		Seroquel	PS	Zeneca Pharmaceutical	ORAL	DRUG GIVEN IN ERROR	
Other	Depressed Level Of Consciousness		Oseltamivir	SS			DRUG USUALLY PRESCRIBED.	
	Hypotension		Hydrocodone Cough Syrup	C				
	Loss Of Consciousness							
	Tachycardia							
	Wrong Drug Administered							

Date:11/14/05ISR Number: 4827556-9Report Type:Expedited (15-DaCompany Report #2005UW15509 Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Interaction		Seroquel	PS	Zeneca Pharmaceutical			
	Road Traffic Accident		Mao Inhibitors	C				
			Methadone	I				

Date:11/14/05ISR Number: 4827585-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20051102786 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Adverse Event		Risperdal	PS				22 MON
	Death		Abilify	SS				22 MON
			Seroquel	SS				22 MON

Date:11/14/05ISR Number: 4827586-7Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20051102788 Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diabetes Mellitus		Risperdal	PS				27 MON
			Zyprexa	SS				27 MON
			Seroquel	SS				27 MON

Date:11/14/05ISR Number: 4827852-5Report Type:Direct Company Report #CTU 262965 Age:88 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diabetes Mellitus		Quetiapine 75 Mg	PS		ORAL	75 MG BID PO	6 MON
	Inadequate Control		Acetaminophen	C				
	Drug Effect Decreased		Claforan	C				
	Glycosylated Haemoglobin Increased		Albuterol	C				
			Cleocin	C				
			Amlodipine	C				
			Levaquin	C				
			Budesonide	C				
			Zosyn	C				
			Enalapril	C				
			Epoetin	C				
			Ipratropium	C				
			Lansoprazole	C				
			Heparin	C				

Date:11/14/05ISR Number: 4827923-3Report Type:Direct Company Report #USP 57416 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Dispensing Error		Sinequan	PS	Pfizer		CAPSULE	
	Medication Error		Seroquel	SS	Astrazeneca		TABLET	
	Somnolence							
	Wrong Drug Administered							

Date:11/14/05ISR Number: 4830002-2Report Type:Expedited (15-DaCompany Report #2005AL004225 Age:43 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Citalopram Hydrobromide					
	Multiple Drug Overdose	Health	Tablets, 40 Mg					
	Intentional	Professional	(Purepac)	PS		ORAL	PO	
			Methadone	SS		ORAL	PO	
			Quetiapine	SS		ORAL	PO	

Date:11/14/05ISR Number: 4830004-6Report Type:Expedited (15-DaCompany Report #2005AL004224 Age:42 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Literature	Alprazolam Tablets					
	Completed Suicide	Health	Usp, 2 Mg (Purepac)	PS		ORAL	PO	
	Multiple Drug Overdose	Professional	Methadone	SS		ORAL	PO	
	Intentional		Quetiapine	SS		ORAL	PO	
	Respiratory Arrest							

Date:11/14/05ISR Number: 4830011-3Report Type:Expedited (15-DaCompany Report #2005AL004069 Age:73 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Propoxyphene Napsylate And					
	Multiple Drug Overdose	Health	Acetaminophen					
	Intentional	Professional	Tablets Usp, 100					
	Substance Abuser		Mg/650 Mg (Purepac)	PS				
			Quetiapine	SS				
			Unknown Chemical	SS				

Date:11/14/05ISR Number: 4830359-2Report Type:Expedited (15-DaCompany Report #2005AL004110 Age:38 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Verapamil Hydrochloride					
	Multiple Drug Overdose	Health	Tablets, 120 Mg					
		Professional	(Purepac)	PS		ORAL	PO	
			Valproic Acid	SS		ORAL	PO	
			Quetiapine	SS		ORAL	PO	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/18/05ISR Number: 4831344-7Report Type:Expedited (15-DaCompany Report #2005PK02140 — Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Bronchopneumonia		Seroquel	PS	Zeneca Pharmaceutical	ORAL		63 DAY
	Dizziness					ORAL		
	Dizziness Postural		Seropram	C				
	Drug Interaction		Amisulpride	C				
	Orthostatic Hypotension		Klacid	I		ORAL		12 DAY

Date:11/18/05ISR Number: 4831347-2Report Type:Expedited (15-DaCompany Report #2005AP05902 — Age:66 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Coma		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
Other	Death							
	Hypotension							

Date:11/18/05ISR Number: 4831921-3Report Type:Expedited (15-DaCompany Report #AU-ROCHE-423869 — Age:45 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Abdominal Distension		Diazepam	PS	Roche	UNKNOWN		
Hospitalization - Initial or Prolonged	Atrioventricular Block First Degree		Doxepin	SS	Roche	UNKNOWN		
	Bradycardia		Clonazepam	SS	Roche	UNKNOWN		
	Cardiac Arrest		Temazepam	SS	Roche	UNKNOWN		
	Depression		Verapamil Sr	SS		UNKNOWN		
	Drug Ineffective		Quetiapine	SS		UNKNOWN		
	Electrocardiogram St Segment Depression							
	Haemodialysis							
	Hypotension							
	Metabolic Acidosis							
	Multiple Drug Overdose							
	Overdose							
	Subendocardial Ischaemia							

Date:11/18/05ISR Number: 4833793-XReport Type:Expedited (15-DaCompany Report #2005-BP-19469RO — Age:42 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Literature	Methadone (Methadone)	PS				
	Completed Suicide	Health	Alprazolam Intensol (Oral Solution (Concentrate)) 1 Mg/Ml (Alprazolam)	SS				
	Multiple Drug Overdose	Professional						
	Intentional		Quetiapine (Quetiapine)	SS				
	Respiratory Arrest							

Date:11/18/05ISR Number: 4833811-9Report Type:Expedited (15-DaCompany Report #2005-BP-19395RO — Age:48 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Literature	Cocaine (Cocaine)	PS				
	Respiratory Arrest	Health	Quetiapine (Quetiapine)	SS				
	Substance Abuse	Professional						

			Gabapentin (Gabapentin)	SS				

Date:11/18/05ISR Number: 4833824-7Report Type:Expedited (15-DaCompany Report #2005-BP-19470RO — Age:43 YR — Gender: — I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature Health Professional	Methadone (Methadone)	PS				
			Citalopram (Citalopram)	SS				
			Quetiapine (Quetiapine)	SS				

Date:11/18/05ISR Number: 4833833-8Report Type:Expedited (15-DaCompany Report #2005-BP-19474RO — Age:46 YR — Gender: — I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest Respiratory Arrest	Literature Health Professional	Methadone (Methadone)	PS				
			Zolpidem (Zolpidem)	SS				
			Quetiapine (Quetiapine)	SS				

Date:11/18/05ISR Number: 4833917-4Report Type:Expedited (15-DaCompany Report #2005-BP-19734RO — Age:60 YR — Gender: — I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide Multiple Drug Overdose Intentional	Literature Health Professional	Diclofenac (Diclofenac)	PS				
			Quetiapine (Quetiapine)	SS				
			Simvastatin (Simvastatin)	SS				

Date:11/18/05ISR Number: 4833940-XReport Type:Direct — Company Report #CTU 263437 — Age:14 YR — Gender:Male — I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening Hospitalization - Initial or Prolonged	Abnormal Behaviour Aggression Bipolar Disorder Drooling Gait Disturbance Increased Appetite Intelligence Test Abnormal Mental Retardation Paralysis Staring Swelling Face Tongue Disorder Tremor Weight Increased		Risperdal	PS			(?UNSURE) 300MG DAILY	
			Seroquel	SS				
			Benadryl	C				
			Depakote	C				
			Viracept	C				
			Epivir	C				
			Zerit	C				

Date:12/29/05ISR Number: 4871313-4Report Type:Expedited (15-DaCompany Report #MK200512-0489-1 — Age:42 YR — Gender:Not SpecifiI/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Literature	Methadose Methadone					
	Completed Suicide	Health	Hy Oral Con Usp	PS	Usp	ORAL	PO	
	Multiple Drug Overdose	Professional	Quetiapine	SS				
	Intentional		Alprazolam	SS				
	Respiratory Arrest							

Date:12/29/05ISR Number: 4871317-1Report Type:Expedited (15-DaCompany Report #MK200512-0492-1 — Age:43 YR — Gender:Not SpecifiI/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Methadose Methadone					
	Multiple Drug Overdose	Health	Hy Oral Con Usp	PS	Usp	ORAL	PO	
	Intentional	Professional	Quetiapine	SS				
			Citalopram	SS				

Date:12/29/05ISR Number: 4871445-0Report Type:Expedited (15-DaCompany Report #MK200512-0499-1 — Age:46 YR — Gender: — I/FU:1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Literature	Methadose@ Methadone					
	Multiple Drug Overdose	Health	Hy Oral Con Usp	PS		ORAL	PO	
	Respiratory Arrest	Professional	Zolpidem	SS				
			Quetiapine	SS				

Date:12/30/05ISR Number: 4869164-XReport Type:Expedited (15-DaCompany Report #2005UW19391 — Age:34 YR — Gender:Female — I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cardiac Arrest		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
	Convulsion		Prolixin	C				

Date:12/30/05ISR Number: 4869165-1Report Type:Expedited (15-DaCompany Report #2005UW19251 — Age:17 YR — Gender:Female — I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blindness Unilateral		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
			Lithium	C				

Date:12/30/05ISR Number: 4869353-4Report Type:Expedited (15-DaCompany Report #2005UW19309 — Age:72 YR — Gender:Male — I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Retinal Haemorrhage		Seroquel	PS	Zeneca Pharmaceutical			

Posture Abnormal

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Seroquel	PS	Zeneca Pharmaceutical	ORAL		
	Seroquel	SS	Zeneca Pharmaceutical	ORAL		
	Aricept	C		ORAL		
	Temazepam	C		ORAL		
	Pravachol	C		ORAL		

Date:06/15/06ISR Number: 5026621-3Report Type:Expedited (15-DaCompany Report #2006AC01090 Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
	Drug Toxicity		Paroxetine	SS				
	Multiple Drug Overdose		Lorazepam	SS				
	Intentional		Valproic Acid	SS				
			Trimethoprim	SS				

Date:06/15/06ISR Number: 5026622-5Report Type:Expedited (15-DaCompany Report #2006AC01092 Age:34 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
	Drug Level Above Therapeutic		Valproic Acid	SS				
	Drug Toxicity							

Date:06/15/06ISR Number: 5026623-7Report Type:Expedited (15-DaCompany Report #2006AC01093 Age:18 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
	Drug Level Above Therapeutic		Bupropion	SS				
	Drug Toxicity		Carbamazepine	SS				
			Diphenhydramine	SS				

Date:06/15/06ISR Number: 5026624-9Report Type:Expedited (15-DaCompany Report #2006AC01097 Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Death		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
	Drug Toxicity		Methadone	SS				
			Nortriptyline	SS				
			Fluoxetine	SS				
			Diazepam	SS				
			Nordiaz	SS				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:06/22/06ISR Number: 5032799-8Report Type:Expedited (15-DaCompany Report #2006UW12982 — Age:58 YR — Gender:Male — I/FU:1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
Other	Suicide Attempt		Seroquel	SS	Zeneca Pharmaceutical	ORAL		
			Prozac	C				
			Prilosec	C				
			Nitroglycerin	C				

Date:06/22/06ISR Number: 5032818-9Report Type:Expedited (15-DaCompany Report #2006UW05682 — Age:53 YR — Gender:Female — I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Sodium Decreased		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
	Condition Aggravated		Cogentin	C		ORAL		
	Convulsion							
	Hypertension							
	Lethargy							
	Neuroleptic Malignant Syndrome							
	Pyrexia							
	White Blood Cell Count Increased							

Date:06/22/06ISR Number: 5032819-0Report Type:Expedited (15-DaCompany Report #2006UW12482 — Age:34 YR — Gender:Female — I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypotension		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
	Overdose							

Date:06/22/06ISR Number: 5032820-7Report Type:Expedited (15-DaCompany Report #2006UW12593 — Age:46 YR — Gender:Male — I/FU:1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dysstasia		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
	Feeling Abnormal		Seroquel	SS	Zeneca Pharmaceutical	ORAL		
	Muscle Spasms		Diabetes Pill	C				
			Cogentin	C				
			Prolixin	C				
			Palexid	C				

Date:06/22/06ISR Number: 5033140-7Report Type:Expedited (15-DaCompany Report #2006UW12810 — Age:40 YR — Gender: — I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Toxicity		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
			Methadone	C		ORAL	30-40 MG	

Date:08/16/06ISR Number: 5081047-1Report Type:Expedited (15-DaCompany Report #2006UW15993 Age:17 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Incorrect Dose Administered		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
	Intentional Overdose		Seroquel	SS	Zeneca Pharmaceutical	ORAL		
	Loss Of Consciousness		Seroquel	SS	Zeneca Pharmaceutical	ORAL		
	Suicide Attempt		Seroquel	SS	Zeneca Pharmaceutical	ORAL		
			Ritalin	C				
			Depakote	C				

Date:08/16/06ISR Number: 5081048-3Report Type:Expedited (15-DaCompany Report #2006AP03318 Age:9683 DY Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased		Seroquel	PS	Zeneca Pharmaceutical	ORAL		16 DAY
	Arthropod Bite		Seroquel	SS	Zeneca Pharmaceutical	ORAL		49 DAY
	Aspartate Aminotransferase Increased		Seroquel	SS	Zeneca Pharmaceutical	ORAL		14 DAY
	Blister		Seroquel	SS	Zeneca Pharmaceutical	ORAL		70 DAY
	Blood Creatine Phosphokinase Increased		Seroquel	SS	Zeneca Pharmaceutical	ORAL		47 DAY
	Drug Eruption		Mailax	C		ORAL		
	Malaise		Wypax	C		ORAL		
	Rhabdomyolysis		Silece	C		ORAL		
	White Blood Cell Count Increased		Pursennid	C		ORAL		
			Amoban	C		ORAL		
			Lendormin	C		ORAL		

Date:08/16/06ISR Number: 5081740-0Report Type:Expedited (15-DaCompany Report #2006AP03775 Age:57 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Alanine Aminotransferase Increased		Seroquel	PS	Zeneca Pharmaceutical	ORAL		7 DAY
	Aspartate Aminotransferase Increased		Seroquel	SS	Zeneca Pharmaceutical	ORAL		2 DAY
	Blood Creatine Phosphokinase Increased		Cercine	C		ORAL		
	Hepatic Function Abnormal		Hydantol F	C		ORAL		
	Hypothermia		Risperidone	C		ORAL		

Date:08/16/06ISR Number: 5081881-8Report Type:Expedited (15-DaCompany Report #2006UW16057 Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
	Drug Toxicity		Seroquel	SS	Zeneca Pharmaceutical	ORAL		
	Hepatic Steatosis		Seroquel	SS	Zeneca			

Restless Legs Syndrome

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Seroquel	PS	Zeneca Pharmaceutical	ORAL		
	Prilosec	C		ORAL		
	Aspirin	C				

Date:08/21/06ISR Number: 5084600-4Report Type:Expedited (15-DaCompany Report #2006UW16088 Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Electrolytes Abnormal		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
Other	Cardiac Arrest		Metoprolol	C				
	Drug Interaction		Vistaril	C				
	Electrocardiogram Qt Prolonged		Altace	C				
	Hypothyroidism		Magnesium Citrate	C				
	Torsade De Pointes		Xanax	C				
			Methadone	I				

Date:08/21/06ISR Number: 5084602-8Report Type:Expedited (15-DaCompany Report #2006UW16386 Age:31 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Pancreatitis		Seroquel	PS	Zeneca Pharmaceutical	ORAL		5 YR
			Depakote	SS				

Date:08/21/06ISR Number: 5087093-6Report Type:Expedited (15-DaCompany Report #DSA_28576_2006 Age:76 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction	Foreign	Orfidal	PS		ORAL	1 MG Q DAY PO	
	Dyskinesia	Health Professional	Deprax	SS		ORAL	100 MG Q DAY PO	
		Other	Seroquel	SS		ORAL	100 MG Q DAY PO	
			Distraneurine	C				
			Ebixa	C				

Date:08/22/06ISR Number: 5085724-8Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20051102786 Age: Gender:Male I/FU:I

Outcome	PT
Death	Aggression
Hospitalization - Initial or Prolonged	Alanine Aminotransferase Increased
	Aspartate Aminotransferase Increased
	Bite
	Compulsions
	Death
	Dyskinesia
	Psychomotor Hyperactivity
	Somnolence

Date:10/10/06ISR Number: 5126493-2Report Type:Expedited (15-DaCompany Report #06H-163-0310536-00 Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Level Above Therapeutic Drug Toxicity Pulmonary Oedema Visceral Oedema	Literature Health Professional	Diazepam Injection (Diazepam) (Diazepam) Diphenhydramine Hcl Injection (Diphenhydramine Hydrochloride Injection) Phenytoin Injection (Phenytoin Sodium Injection) (Phenytoin Sodium) (Phenytoin Sodium) Quetiapine (Quetiapine)	PS SS SS SS				

Date:10/10/06ISR Number: 5126494-4Report Type:Expedited (15-DaCompany Report #06H-163-0310539-00 Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Toxicity Pulmonary Oedema	Literature Health Professional	Diazepam Injection (Diazepam) (Diazepam) Quetiapine (Quetiapine) Methadone (Phenytoin Sodium Injection) (Methadone) Nortriptyline (Diazepam Injection) (Nortriptyline) Fluoxetine (Fluoxetine)	PS SS SS SS SS				

Date:10/10/06ISR Number: 5126500-7Report Type:Expedited (15-DaCompany Report #2006104942 Age:35 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abnormal Behaviour Anger Disturbance In Attention Hypersomnia Lethargy Mania Vomiting	Consumer	Chantix Tablets (Varenicline) Paxil (Paroxetine Hydrochloride) Seroquel (Quetiapine Fumarate)	PS SS SS			1.5 MG (2 IN 1 D)	

Date:10/11/06ISR Number: 5124787-8Report Type:Expedited (15-DaCompany Report #2006DW19170 Age:2 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Accidental Drug Intake By Child Medication Error		Seroquel	PS	Zeneca Pharmaceutical	ORAL		1 DAY

Drug Hypersensitivity Neuroleptic Malignant Syndrome	Report Source	Product Quetiapine	Role PS	Manufacturer	Route ORAL	Dose 50 MG PO Q6PM	Duration

Date:10/17/06ISR Number: 5132043-7Report Type:Expedited (15-DaCompany Report #2006123273 Age: Gender:Female I/FU:I

Outcome Other	PT Amnesia	Report Source Health Professional	Product Depo-Provera Suspension, Sterile (Medroxyprogesterone Acetate) Klonopin (Clonazepam) Lamictal (Lamotrigine) Seroquel (Quetiapine Fumarate)	Role PS SS SS SS	Manufacturer	Route	Dose -	Duration

Date:10/18/06ISR Number: 5129478-5Report Type:Expedited (15-DaCompany Report #2006UW15289 Age:53 YR Gender:Male I/FU:F

Outcome Hospitalization - Initial or Prolonged Other	PT Anaemia Drug Toxicity Leukopenia	Report Source	Product Seroquel Ribavirin Interferon Clonazepam Insulin Lasix Potassium Chloride Actos Lisinopril Tricor Yalatan Aranesp Nasonex Vitamin B 12 Vitamin B 6 Folic Acid	Role PS C C C C C C C C C C C C C C C C	Manufacturer Zeneca Pharmaceutical	Route ORAL	Dose 0.5-2MG	Duration

Date:10/18/06ISR Number: 5129649-8Report Type:Expedited (15-DaCompany Report #US-ROCHE-466418 Age:41 YR Gender:Female I/FU:I

Outcome Death	PT Affect Lability Aggression Anxiety Drug Interaction Drug Toxicity Hypomania Somnolence	Report Source	Product Klonopin Lithium Prevacid Methadone Seroquel	Role PS C C I I	Manufacturer Roche	Route ORAL UNKNOWN UNKNOWN	Dose	Duration

	Increased Blood Alkaline Phosphatase Increased Blood Bilirubin Increased Gamma-Glutamyltransferase Increased Hepatic Enzyme Increased	Report Source	Product Seroquel	Role PS	Manufacturer Zeneca Pharmaceutical	Route ORAL	Dose	Duration 1 YR

Date:10/20/06ISR Number: 5131307-0Report Type:Expedited (15-DaCompany Report #2006GB01808 Age: Gender:Female I/FU:1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Delirium Depressed Level Of Consciousness Drug Interaction Malaise Mydriasis Vision Blurred		Seroquel Nardil Sertraline	PS I I	Zeneca Pharmaceutical	ORAL		

Date:10/20/06ISR Number: 5131484-1Report Type:Expedited (15-DaCompany Report #2006UW20169 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Depressed Level Of Consciousness Feeling Abnormal Ill-Defined Disorder		Seroquel Methadone Unspecified	PS C C	Zeneca Pharmaceutical	ORAL		

Date:10/20/06ISR Number: 5131628-1Report Type:Expedited (15-DaCompany Report #2006UW19917 Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dyskinesia Extrapyramidal Disorder Gait Disturbance		Seroquel Seroquel	PS SS	Zeneca Pharmaceutical Zeneca Pharmaceutical	ORAL ORAL		1 YR

Date:10/20/06ISR Number: 5131629-3Report Type:Expedited (15-DaCompany Report #2006PK02081 Age:262 MON Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Death Metabolic Disorder Optic Neuritis Visual Field Defect Visual Impairment		Seroquel	PS	Zeneca Pharmaceutical	ORAL		

Date:10/23/06ISR Number: 5132971-2Report Type:Expedited (15-DaCompany Report #2006UW19890 Age:54 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diabetes Mellitus Small Intestine Carcinoma		Seroquel Chemotherapy Radiation Therapy	PS C C	Zeneca Pharmaceutical	ORAL		2 YR

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/02/06ISR Number: 5142754-5Report Type:Expedited (15-DaCompany Report #2006UW20771 Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Bradycardia		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
	Extrasystoles							
	Intentional Overdose		Digoxin	SS				
	Ventricular Arrhythmia							

Date:11/02/06ISR Number: 5142755-7Report Type:Expedited (15-DaCompany Report #2006UW20757 Age:80 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Confusional State		Seroquel	PS	Zeneca Pharmaceutical	ORAL		2 YR
	Depressed Level Of Consciousness		Ec-Asa	C				
	Hyperhidrosis		Epival	C				
	Hypertonia		Hydrochlorothiazide	C				
	Neuroleptic Malignant Syndrome		L-Thyroxine	C				
	Pyrexia							
	Tremor							

Date:11/02/06ISR Number: 5142756-9Report Type:Expedited (15-DaCompany Report #2006UW20967 Age:41 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abnormal Behaviour		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
	Drug Interaction		Lithium	C				
	Drug Toxicity		Prevacid	C		ORAL		20 DAY
			Klonopin	I				689 DAY
			Methadone	I				

Date:11/02/06ISR Number: 5142757-0Report Type:Expedited (15-DaCompany Report #2006UW20742 Age:43 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Rash		Seroquel	PS	Zeneca Pharmaceutical	ORAL		1 MON
	Urticaria		Tylenol Arthritis Pain	C				

Date:11/03/06ISR Number: 5143037-XReport Type:Expedited (15-DaCompany Report #2006PK02081 Age:262 MON Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Gastritis		Seroquel	PS	Zeneca Pharmaceutical	ORAL		4 YR
Hospitalization - Initial or Prolonged	Gastroenteritis		Allopurinol	C				
	Metabolic Acidosis		Biocarn	C		INTRAVENOUS		
	Nausea		Biocarn	C		INTRAVENOUS		1 WK
	Optic Neuritis		Biocarn	C				
	Vomiting		Cotrimoxazol	C				
			Colistin	C				
			Lgg	C				3 DAY
			Urbason	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/09/06ISR Number: 5150253-XReport Type:Direct Company Report #CTU 288896 Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Neutropenia		Seroquel	PS		ORAL	50MG QAM PO	
			Seroquel	SS		ORAL	100MG QHS PO	

Date:11/09/06ISR Number: 5151647-9Report Type:Expedited (15-DaCompany Report #DSA_61249_2006 Age:53 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	uration
Death	Cardiac Arrest	Literature	Diazepam	PS		ORAL	PO	
	Drug Abuser	Health	Methadone	SS		ORAL	PO	
	Respiratory Arrest	Professional	Quetiapine	SS		ORAL	PO	

Date:11/09/06ISR Number: 5151710-2Report Type:Expedited (15-DaCompany Report #PAR_1040_2006 Age:53 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Literature	Diazepam	PS		ORAL	DF PO	
	Drug Abuser	Health	Methadone	SS		ORAL	DF PO	
	Respiratory Arrest	Professional	Quetiapine	SS		ORAL	DF PO	

Date:11/10/06ISR Number: 5147719-5Report Type:Expedited (15-DaCompany Report #2006UW21681 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Faecaloma		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
			Lithium	SS				

Date:11/10/06ISR Number: 5147721-3Report Type:Expedited (15-DaCompany Report #2006UW15030 Age:708 MON Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cogwheel Rigidity		Seroquel	PS	Zeneca Pharmaceutical	ORAL	400 TO 500 MG	35 MON
Other	Fall					ORAL	60 TO 120 MG	
	Gait Disturbance		Cymbalta	C		ORAL		
	Musculoskeletal Stiffness		Depakote	C				
	Parkinsonism		Effexor	C				

Date:11/10/06ISR Number: 5147722-5Report Type:Expedited (15-DaCompany Report #2006UW21518 Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Lip Swelling		Seroquel	PS	Zeneca Pharmaceutical	ORAL	12.5 MG AM, 50 MG PM	6 DAY
	Oedema Mouth							6 DAY
	Swelling Face							
	Tongue Paralysis		Lithium	C				

Date:11/10/06ISR Number: 5147828-0Report Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-13124730 Age:49 YR Gender:Male I/FU:F

Outcome
Hospitalization -
Initial or Prolonged

BEDTIME PO

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

Date:11/15/06ISR Number: 5156666-4Report Type:Expedited (15-DaCompany Report #T200601275

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Affect Lability	Health	Methadone	PS		ORAL	40 MG, QD, ORAL	
	Aggression	Professional						
	Agitation		Klonopin (Clonazepam)	SS		ORAL	1 MG, TID, ORAL	
	Anger							
	Anxiety		Seroquel	SS				
	Drug Interaction		Lithium (Lithium)	C				
	Drug Toxicity		Prevacid (Lansoprazole)	C				
	Hallucination, Auditory							
	Hypomania							
	Irritability							
	Paranoia							
	Somnolence							
	Treatment Noncompliance							

Age:38 YR Gender: I/FU:I

Date:11/15/06ISR Number: 5156686-XReport Type:Expedited (15-DaCompany Report #PAR_0976_2006

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Doxepin	PS		ORAL	DF PO	
	Poisoning	Health	Quetiapine	SS		ORAL	DF PO	
		Professional	Cocaine	SS			DF	
			Unknown	C				

Age:44 YR Gender: I/FU:I

Date:11/15/06ISR Number: 5156687-1Report Type:Expedited (15-DaCompany Report #PAR_0975_2006

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest	Literature	Doxepin	PS		ORAL	DF PO	
	Completed Suicide	Health	Mirtazapine	SS		ORAL	DF PO	
	Poisoning	Professional	Quetiapine	SS		ORAL	DF PO	
	Respiratory Arrest		Unknown	C				

Age: Gender:Male I/FU:I

Date:11/16/06ISR Number: 5152017-XReport Type:Expedited (15-DaCompany Report #US-JNJFOC-20051102786

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Bite		Risperdal	PS		ORAL	initially started at 0.5 mg every 4 hours prn,	
Hospitalization - Initial or Prolonged	Compulsions						1 mg daily	
	Death					ORAL	1 mg AM, mid-day, and 2 mg HS daily	22 MON
	Dyskinesia		Risperdal	SS		ORAL	0.5 mg AM, mid-day, and 2 mg HS daily	22 MON
	Psychomotor Hyperactivity		Risperdal	SS				
	Somnolence		Abilify	SS			titrated to	
	Thirst		Abilify	SS				
			Seroquel	SS				
			Seroquel	SS				

Date:12/13/06ISR Number: 5277450-7Report Type:Periodic Company Report #2006UWU6495 Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Pancreatitis	Consumer	Seroquel	PS		ORAL	650 MG DAILY PO	
			Prozac	C				
			Clonapin	C				
			Nexium	C				
			Synthroid	C				
			Promethazine	C				
			Zyprexa	C				

Date:12/13/06ISR Number: 5277451-9Report Type:Periodic Company Report #2004UW10570 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Convulsion	Health Professional	Seroquel	PS				

Date:12/13/06ISR Number: 5277452-0Report Type:Periodic Company Report #2005UW17066 Age:46 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage	Hyponatraemia	Health Professional	Seroquel	PS			50 MG BID/200 MG HS	
			Trazodone	C				
			Propranolol	C				

Date:12/13/06ISR Number: 5277453-2Report Type:Periodic Company Report #2006UWU6554 Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hypotension	Health Professional	Seroquel	PS		ORAL	50 MG PO	
			Methadone	C				

Date:12/13/06ISR Number: 5277455-6Report Type:Periodic Company Report #2006UW06655 Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Diabetes Mellitus	Consumer	Seroquel	PS				
	Ill-Defined Disorder		Lithium	C				
	Nightmare		Xanax	C				
	Rectal Haemorrhage		Ritalin	C				
	Vision Blurred		Clonazepam	C				

Date:12/13/06ISR Number: 5277456-8Report Type:Periodic Company Report #2004UW10798 Age:29 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Akathisia	Health Professional	Seroquel	PS		ORAL	25 MG PO	

Date:02/12/07ISR Number: 5239595-7Report Type:Expedited (15-DaCompany Report #2007AP000078 — Age:30 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Constipation Dehydration Hallucination Mania Pain Poisoning Restlessness		Apo-Divalproex (Valproate Semisodium)	PS		ORAL	1000 MG; HS; PO	
			Quetiapine Fumarate (Quetiapine Fumarate)	SS				

Date:02/12/07ISR Number: 5241233-4Report Type:Direct Company Report #CTU 295668 — Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Vertigo Vision Blurred		Quetiapine 25 Mg	PS		ORAL	75 MG QD PO	

Date:02/12/07ISR Number: 5241266-8Report Type:Expedited (15-DaCompany Report #2006RR-04738 — Age:27 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Multiple Drug Overdose	Foreign Health Professional Other	Paracetamol (Paracetamol) Unknown	PS				
			Cannabis (Cannabis)	SS		ORAL	200 MG, BID, ORAL	
			Seroquel (Seroquel)	SS				
			Paroxetine (Paroxetine)	C				

Date:02/12/07ISR Number: 5242100-2Report Type:Expedited (15-DaCompany Report #2007-00513 — Age:53 YR Gender:Unknown I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest	Literature Health Professional	Diazepam (Watson Laboratories) (Diazepam) Tablet	PS	Watson Laboratories			
			Methadone (Methadone)	SS				
			Quetiapine (Quetiapine)	SS				

Date:02/13/07ISR Number: 5237007-0Report Type:Expedited (15-DaCompany Report #2007SE00738 — Age:690 MON Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Agitation Intentional Overdose Loss Of Consciousness Suicide Attempt Unresponsive To Stimuli		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
			Seroquel	SS	Zeneca Pharmaceutical	ORAL		
			Amoxycylin	SS		ORAL		
			Antiemetics	C		ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/26/07ISR Number: 5499493-0Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2007UW02182 Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain		Seroquel	PS	Zeneca Pharmaceutical	ORAL		65 MON
	Arthralgia							
	Back Pain		Navane	C				
	Caesarean Section		Risperdal	C				
	Dizziness							
	Nausea							
	Oropharyngeal Pain							
	Skin Laceration							
	Subcutaneous Abscess							
	Tonsillectomy							
	Type 2 Diabetes Mellitus							
	Uterine Haemorrhage							
	Vomiting							

Date:10/26/07ISR Number: 5499510-8Report Type:Expedited (15-DaCompany Report #US-ROCHE-526534 Age:53 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest		Diazepam	PS	Roche	ORAL	EXPOSURE ACUTE ON CHRONIC.	
Other	Drug Abuser							
	Respiratory Arrest		Methadone	SS		ORAL	EXPOSURE ACUTE ON CHRONIC.	
			Quetiapine	SS		ORAL	EXPOSURE ACUTE ON CHRONIC.	
			Unspecified Drugs	SS		ORAL	EXPOSURE ACUTE ON CHRONIC.	

Date:10/26/07ISR Number: 5499588-1Report Type:Expedited (15-DaCompany Report #CA-ASTRAZENECA-2007UW24398 Age:38 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anorgasmia		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
	Libido Decreased					ORAL		
	Sexual Dysfunction		Topamax	C				

Date:10/26/07ISR Number: 5499601-1Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2007UW17014 Age:18007 DYGender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Nephrolithiasis		Seroquel	PS	Zeneca Pharmaceutical	ORAL		155 DAY
	Obstruction Gastric		Seroquel	SS	Zeneca Pharmaceutical	ORAL		155 DAY
	Pancreatitis		Seroquel	SS	Zeneca Pharmaceutical	ORAL		628 DAY
	Type 2 Diabetes Mellitus		Seroquel	SS	Zeneca Pharmaceutical	ORAL		628 DAY
	Urethral Stenosis		Seroquel	SS	Zeneca Pharmaceutical	ORAL		768 DAY
	Weight Increased		Seroquel	SS	Zeneca Pharmaceutical	ORAL		768 DAY

Date:03/14/08ISR Number: 5664617-9Report Type:Expedited (15-DaCompany Report #JP-ASTRAZENECA-2008AP01843

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Loss Of Consciousness Overdose		Seroquel	PS	Zeneca Pharmaceutical	ORAL		

Date:03/14/08ISR Number: 5664618-0Report Type:Expedited (15-DaCompany Report #NZ-ASTRAZENECA-2008AC00636

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Congestive Cardiomyopathy Pneumonia Pulmonary Embolism		Quetiapine	PS	Zeneca Pharmaceutical			
			Quetiapine	SS	Zeneca Pharmaceutical			
			Citalopram	C				
			Citalopram	C				
			Benztropine	C				
			Benztropine	C				

Date:03/14/08ISR Number: 5664734-3Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2008UW05031

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Poisoning Headache Obstructive Airways Disorder Road Traffic Accident		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
			Effexor	SS				
			Xanax	C				
			Valium	C				
			Topamax	C				
			Methadone	C				

Date:03/14/08ISR Number: 5664782-3Report Type:Expedited (15-DaCompany Report #BR-ASTRAZENECA-2008UW04991

Age:11 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Other	Abdominal Distension Aspiration Bronchial Dyspnoea Pneumonitis Chemical Respiratory Failure Sepsis Vomiting		Seroquel	PS	Zeneca Pharmaceutical	ORAL ORAL ORAL ORAL		
			Tegretol	C				
			Leucogen	C				
			Topamax	C				

Date:03/14/08ISR Number: 5670367-5Report Type:Direct Company Report #CTU 328787

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Cerebrovascular Accident Headache Pain		Seroquel 50mg John Hopskins	PS	John Hopskins	ORAL	1 TABLET 1 TIMES A DAY PO	

		Pharmaceutical	ORAL		
Seroquel	SS	Zeneca Pharmaceutical	ORAL		
Seroquel	SS	Zeneca Pharmaceutical	ORAL	200-800MG	
Seroquel	SS	Zeneca Pharmaceutical	ORAL	200-800MG	
Risperdal	C		ORAL		10 YR

Date:03/19/08ISR Number: 5673113-4Report Type:Expedited (15-DaCompany Report #NL-ASTRAZENECA-2008AC00694 Age:9230 DY Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Follicle Stimulating Hormone Increased		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
	Blood Luteinising Hormone Increased		Cisordinol	SS				
			Temesta	SS				
			Alprazolam	SS				

Date:03/19/08ISR Number: 5673277-2Report Type:Expedited (15-DaCompany Report #DE-ASTRAZENECA-2008PK00564 Age:86 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
			Seroquel	SS	Zeneca Pharmaceutical	ORAL		
			Risperdal	SS				

Date:03/20/08ISR Number: 5674043-4Report Type:Expedited (15-DaCompany Report #US-WYE-H03044608 Age: Gender:Female I/FU:1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Asphyxia		Effexor Xr	PS	Wyeth Pharmaceuticals Inc.	ORAL		
	Drug Toxicity		Effexor Xr	SS	Wyeth Pharmaceuticals Inc.	ORAL		
	Fall		Methadone	SS	Unknown		unknown	
	Loss Of Consciousness		Xanax	SS	Upjohn Company, The		unknown	
	Oedema		Diazepam	SS	Unknown		unknown	
			Seroquel	SS	Unknown		unknown	
			Topamax	SS	Janssen-Cilag		unknown	

Date:03/20/08ISR Number: 5674785-0Report Type:Expedited (15-DaCompany Report #AU-ASTRAZENECA-2007AP04399 Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diabetes Mellitus		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
	Overdose		Seroquel	SS	Zeneca Pharmaceutical	ORAL		
	Weight Increased		Zuclopenthixol	C				
			Zuclopenthixol	C				

Date:05/08/08ISR Number: 5731912-4Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2008UW08919

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Prolactin Increased		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
	Breast Discharge		Clonazepam	C		ORAL		
			Cymbalta	C				
			Artane	C				
			Statin Therapy	C				
			Thyroid Therapy	C				

Date:05/08/08ISR Number: 5732011-8Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2008UW09023

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
	Blood Pressure Decreased		Inderal	SS				
	Lethargy							
	Syncope							

Date:05/08/08ISR Number: 5732143-4Report Type:Expedited (15-DaCompany Report #US-ABBOTT-08P-163-0437462-00

Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Congenital Anomaly	Atrial Septal Defect		Norvir Soft Gelatin Capsules	PS		TRANSPLACENTAL		
Other	Drug Exposure During Pregnancy		Truvada	SS		TRANSPLACENTAL		
	Drug Withdrawal Syndrome Neonatal		Atazanavir Sulfate	SS		TRANSPLACENTAL		
	Left Ventricular Dysfunction		Zidovudine	SS		TRANSPLACENTAL		
	Mitral Valve Incompetence		Hydroxyzine	SS		TRANSPLACENTAL		
	Respiratory Depression		Quetiapine	SS		TRANSPLACENTAL		
	Supraventricular Tachycardia		Methadone	SS		TRANSPLACENTAL		
	Tricuspid Valve Incompetence		Zidovudine	C				
	Wolff-Parkinson-White Syndrome							

Date:05/08/08ISR Number: 5736824-8Report Type:Expedited (15-DaCompany Report #DSA_30923_2007

Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Dysarthria	Foreign Health Professional Other	Tavor (Lorazepam)	PS		ORAL	(1 MG QD ORAL)	
	Medication Error		Seroquel (Quetiapine)	SS		ORAL	(3 DF QD ORAL)	
	Multiple Drug Overdose Accidental		Tricyclic Antidepressants	SS		ORAL	(DF ORAL)	
			Lsd	SS				
			Methadone	SS				
			Amphetamine Salts	SS				

Date:06/06/08ISR Number: 5760867-1Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2008UW11026 Age:13 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abdominal Pain Upper		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
	Amnesia							
	Bipolar Disorder		Paxil	C				
	Disturbance In Attention							
	Irritability							
	Suicidal Ideation							
	Tremor							
	Trichotillomania							

Date:06/06/08ISR Number: 5761010-5Report Type:Expedited (15-DaCompany Report #DE-ASTRAZENECA-2008PK01186 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Leukopenia		Seroquel Prolong	PS	Zeneca Pharmaceutical	ORAL		
			Haloperidol	SS		ORAL		

Date:06/06/08ISR Number: 5761044-0Report Type:Expedited (15-DaCompany Report #ES-ASTRAZENECA-2008AC01414 Age:44 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypernatraemia		Seroquel	PS	Zeneca Pharmaceutical	ORAL		2 YR
			Epilexter	SS		ORAL		2 MON
			Prozac	SS		ORAL		2 YR
			Benexol	C				
			Legalon	C				
			Levothroid	C				
			Rivotril	C				

Date:06/06/08ISR Number: 5761249-9Report Type:Expedited (15-DaCompany Report #BE-ASTRAZENECA-2008AC01427 Age:34 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Paralysis		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
			Dafalgan Codeine	C				

Date:06/06/08ISR Number: 5761250-5Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2007UW10974 Age:14793 DYGender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death		Seroquel	PS	Zeneca Pharmaceutical	ORAL		519 DAY
	Type 2 Diabetes Mellitus							

Date:06/06/08ISR Number: 5761280-3Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2008UW11338 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Arrhythmia		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
	Overdose		Methadone	SS				

Infrequent Bowel Movements							
Oliguria	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Pancreatic Cyst		Seroquel	PS	Uns	ORAL		36 MON
Pancreatitis Chronic		Seroquel	SS	Uns	ORAL		36 MON
Thrombosis		Lithium	C				62 MON
Vomiting		Wellbutrin	C				62 MON

Date:07/31/08ISR Number: 5828501-XReport Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2008UW11400 Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Sodium Decreased		Seroquel	PS	Uns	ORAL		
Other	Inappropriate Antidiuretic Hormone Secretion		Depakote	C				
	Water Intoxication							

Date:07/31/08ISR Number: 5828516-1Report Type:Expedited (15-DaCompany Report #AU-ASTRAZENECA-2008AP05720 Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Creatine Phosphokinase Increased		Quetiapine Fumarate	PS		ORAL		
	Electrocardiogram Abnormal		Pimozide	SS				
	Neutrophil Count Increased		Amisulpride	SS				
	Tachycardia							
	White Blood Cell Count Increased							

Date:07/31/08ISR Number: 5828571-9Report Type:Expedited (15-DaCompany Report #AU-ASTRAZENECA-2007AP05925 Age:11326 DYGender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Gait Disturbance		Seroquel	PS	Uns	ORAL	25-50 MG	
	Oculogyric Crisis		Luvox	C		ORAL	LONG TERM USER	

Date:07/31/08ISR Number: 5828713-5Report Type:Expedited (15-DaCompany Report #GB-ASTRAZENECA-2008GB01145 Age:21581 DYGender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Decreased		Seroquel	PS	Uns	ORAL		3 DAY
	Dysphagia		Lithium	C		ORAL		
	Fall		Depakote	C		ORAL		
	Somnolence		Diazepam	C		ORAL		
			Zopiclone	C		ORAL		26 DAY

Date:07/31/08ISR Number: 5828816-5Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2008UW11338 Age: Gender: I/FU:F

Outcome	PT
Death	Electrocardiogram Qt Prolonged

Visual Acuity Reduced Weight Decreased Weight Increased	Report Source	Product Seroquel Seroquel	Role Manufacturer PS SS	Route ORAL ORAL	Dose	Duration 2 YR	

Date:09/18/08ISR Number: 5888178-4Report Type:Expedited (15-DaCompany Report #JP-ASTRAZENECA-2008AP07251

Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role Manufacturer	Route	Dose	Duration
Other	Cardiac Arrest		Seroquel	PS	ORAL	SEROQUEL PRESCRIBED FOR PATIENT'S SON/DAUGHTER	1 DAY

Date:09/18/08ISR Number: 5888194-2Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2008UW19092

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

Outcome	PT	Report Source	Product	Role Manufacturer	Route	Dose	Duration
Other	Agranulocytosis		Seroquel Depakote	PS C	ORAL		

Date:09/18/08ISR Number: 5888198-XReport Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2008UW19248

Age:68 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role Manufacturer	Route	Dose	Duration
Death	Completed Suicide Overdose		Seroquel Acetaminophen Benzodiazepine Gabapentin Primidone	PS SS SS SS SS	ORAL ORAL ORAL ORAL ORAL		

Date:09/18/08ISR Number: 5888249-2Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2008UW18986

Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role Manufacturer	Route	Dose	Duration
Other	Drug Interaction Hypotension		Seroquel Lopressor Methadone	PS C I	ORAL		

Date:09/18/08ISR Number: 5888270-4Report Type:Expedited (15-DaCompany Report #CH-ASTRAZENECA-2008PK02044

Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role Manufacturer	Route	Dose	Duration
Death	Death		Seroquel	PS	ORAL		98 DAY
			Seroquel	SS	ORAL		10 DAY
			Seroquel	SS	ORAL		8 DAY
			Seroquel	SS	ORAL		10 DAY
			Seroquel	SS	ORAL		13 DAY
			Seroquel	SS	ORAL		22 DAY
			Seroquel	SS	ORAL		10 DAY
			Seroquel	SS	ORAL		6 DAY
			Fluanxol	SS	ORAL		11 DAY
			Fluanxol	SS	ORAL		21 DAY
			Fluanxol	SS	ORAL		47 DAY
			Temesta	C			

Date:11/06/08ISR Number: 5943618-7Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2008AC02861 Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Toxicity		Quetiapine	PS				
	Multiple Drug Overdose		Methadone	SS				
			Dextromethorphan	SS				
			Promethazine	SS				

Date:11/06/08ISR Number: 5943623-0Report Type:Expedited (15-DaCompany Report #US-PFIZER INC-2007051662 Age:44 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Memory Impairment		Nardil	PS				
	Mental Disorder		Geodon	SS				
			Lamictal	SS				
			Abilify	SS				
			Quetiapine	SS				
			Synthroid	C				
			Multivitamins	C				

Date:11/06/08ISR Number: 5943682-5Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20070104789 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Aggression		Risperdal	PS				
Other	Agitation		Seroquel	SS				
	Akathisia		Olanzapine	SS				
	Anxiety		Risperdal	SS				
	Gynaecomastia		Zoloft	C				
	Hostility		Clonidine	C				
	Hyperprolactinaemia							
	Impulsive Behaviour							
	Mastectomy							
	Suicidal Ideation							
	Type 1 Diabetes Mellitus							

Date:11/06/08ISR Number: 5943683-7Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20070100240 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diabetes Mellitus		Risperdal	PS				
	Photophobia		Seroquel	SS				

Date:11/06/08ISR Number: 5943779-XReport Type:Expedited (15-DaCompany Report #FI-ASTRAZENECA-2008SE05066 Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Neutrophil Count Decreased		Seroquel	PS		ORAL		
	White Blood Cell Count Decreased							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:11/07/08ISR Number: 5945072-8Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2008UW24661 Age:17 YR Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Accidental Overdose		Seroquel	PS		ORAL	POSSIBLE SEROQUEL OVERDOSE	
	Intentional Drug Misuse							
	Malaise							
	Wrong Drug Administered							

Date:11/07/08ISR Number: 5945315-0Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2008AC02861 Age:48 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Toxicity		Quetiapine	PS		ORAL		
	Multiple Drug Overdose		Methadone	SS		ORAL		
			Dextromethorphan	SS		ORAL		
			Promethazine	SS		ORAL		
			Diazepam	SS		ORAL		

Date:11/07/08ISR Number: 5945656-7Report Type:Expedited (15-DaCompany Report #US-PFIZER INC-2008093395 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Psychiatric Symptom		Chantix Tablets	PS				
			Seroquel	SS				
			Effexor	SS				
			Citalopram	C				
			Clonazepam	C				
			Reyataz	C				
			All Other Therapeutic Products	C				
			Epivir	C				
			Acetylsalicylic Acid	C				
			Lipitor	C				
			Lisinopril	C				
			All Other Therapeutic Products	C				
			Abilify	C				

Date:11/07/08ISR Number: 5946919-1Report Type:Direct Company Report #CTU 355414 Age:83 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypotonia		Seroquel 200mg	PS		ORAL	200MG EVERY 8 HOURS PO	
	Inappropriate Schedule Of Drug Administration		Seroquel 50 Mg	SS		ORAL	150 MG TWICE DAILY PO	
	Muscle Rigidity							
	Restless Legs Syndrome							
	Tremor							

Date:11/07/08ISR Number: 5947660-1Report Type:Expedited (15-DaCompany Report #1000001575 Age:42 YR Gender:Male I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Condition Aggravated
	Drug Interaction
	Gamma-Glutamyltransferase Increased

Date:01/08/09ISR Number: 6034217-XReport Type:Expedited (15-DaCompany Report #8040757

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Hydrocodone/Acetamin					
	Intentional Drug Misuse	Health	ophen	PS				
		Professional	Quetiapine	SS				
			Clonazepam	SS				
			Sertraline	SS				
			Pregabalin	SS				
			Carisoprodol	SS				

Date:01/08/09ISR Number: 6034231-4Report Type:Expedited (15-DaCompany Report #80402799

Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Hydrocodone					
	Intentional Drug Misuse	Health	Bitartrate And					
		Professional	Acetaminophen	PS				
			Carisoprodol	SS				
			Quetiapine	SS				
			Zolpidem	SS				

Date:01/08/09ISR Number: 6034530-6Report Type:Expedited (15-DaCompany Report #000053

Age:50 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Methocarbamol	PS				
	Intentional Drug Misuse	Health	Quetiapine	SS				
		Professional	Benzodiazepine					
		Other	Derivatives	SS				
			Maprotiline	SS				
			Hydrocodone	SS				
			Tramadol	C				

Date:01/08/09ISR Number: 6034560-4Report Type:Expedited (15-DaCompany Report #8040801

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide	Literature	Acetaminophen-Hydroc					
	Intentional Drug Misuse	Health	odone	PS				
		Professional	Marijuana	SS				
			Lithium	SS				
			Sertraline	SS				
			Quetiapine	SS				
			Diphenhydramine	SS				
			Methadone	SS				
			Clonazepam	SS				

Date:01/08/09ISR Number: 6034663-4Report Type:Expedited (15-DaCompany Report #PAR_02487_2008

Age:12 YR Gender:Female I/FU:I

Outcome	PT
Death	Aspiration
	Brain Oedema
	Multiple Drug Overdose
	Accidental
	Self-Medication

Flexeril	SS	
Lamictal	SS	
Cogentin	SS	UNKNOWN
Lexapro	C	
Albuterol	C	

Date:01/16/09ISR Number: 6039794-0Report Type:Expedited (15-DaCompany Report #US-ABBOTT-09P-163-0497881-00 Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest		Valproic Acid	PS			Ingestion + unknown	
			Quetiapine	SS			Ingestion + unknown	

Date:01/16/09ISR Number: 6039853-2Report Type:Expedited (15-DaCompany Report #US-ABBOTT-09P-163-0497712-00 Age:48 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest		Valproic Acid	PS			Route - ingestion	
			Quetiapine	SS			Route - ingestion	

Date:01/16/09ISR Number: 6039857-XReport Type:Expedited (15-DaCompany Report #US-ABBOTT-09P-163-0497813-00 Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest		Levothyroxine	PS			Ingestion	
			Bupropion	SS			Ingestion	
			Quetiapine	SS			Ingestion	
			Baclofen	SS			Ingestion	
			Promethazine	SS			Ingestion	
			Methadone	SS			Ingestion	
			Duloxetine	SS			Ingestion	
			Clonazepam	SS			Ingestion	
			Zolpidem	SS			Ingestion	
			Lithium	SS			Ingestion	
			Lamotrigine	SS			Ingestion	
			Efavirenz	SS			Ingestion	
			Emtricitabine W/Tenofovir	SS			Ingestion	

Date:01/16/09ISR Number: 6039901-XReport Type:Expedited (15-DaCompany Report #US-ABBOTT-09P-163-0497820-00 Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide		Levothyroxine	PS			Ingestion	
			Quetiapine	SS			Ingestion	
			Mirtazapine	SS			Ingestion	
			Trazodone	SS			Ingestion	
			Gabapentin	SS			Ingestion	
			Topiramate	SS			Ingestion	
			Hydroxyzine	SS			Ingestion	
			Ezetimibe	SS			Ingestion	

Date:02/03/09ISR Number: 6064410-1Report Type:Dire t Company Report #CTU 364894 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Atrioventricular Block First Degree		Seroquel (Quetiapine)	PS			200MG TABLET 200 MG QHS ORAL	
			Cymbalta (Duloxetine)	C				
			Effexor Sr (Venlafaxine Extended Release)	C				
			Lamictal (Lamotrigine)	C				
			Lithium Carbonate Sustained Release	C				
			Multivitamin Therapeutic (Therapeutic Multivitamins)	C				
			Neurontin (Gapapentin)	C				
			Provigil (Modafinil)	C				
			Simvastatin	C				
			Verapamil Hcl	C				
			Vitamin B12 (Cyanocobalamin)	C				

Date:02/03/09ISR Number: 6066777-7Report Type:Expedited (15-DaCompany Report #2009S1000090 Age:23 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Aspiration Body Temperature Increased Completed Suicide Convulsion Delirium Drug Toxicity Electromechanical Dissociation Flushing Foreign Body Heart Rate Increased Hyperhidrosis Hypertonia Hypotension Multiple Drug Overdose Needle Track Marks Opisthotonus Respiratory Arrest Skin Warm	Literature Health Professional	Roxanol Methadone Bupropion Cocaine Benzodiazepine Quetiapine Cyclobenzaprine Marijuana	PS SS SS SS SS SS SS SS				

Date:02/03/09ISR Number: 6067868-7Report Type:Expedited (15-DaCompany Report #2009-190002-NL Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source
Death	Completed Suicide	Literature Health

Laboratories)	SS	Watson Laboratories		UNK	
Quetiapine	SS				

Date:02/04/09ISR Number: 6065399-1Report Type:Expedited (15-DaCompany Report #US-WATSON-2009-00574 Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest		Buspirone Hydrochloride (Watson Laboratories)	PS	Watson Laboratories		unknown	
			Hydroxyzine Hydrochloride (Watson Laboratories)	SS	Watson Laboratories		UNK	
			Cyclobenzaprine Hydrochloride (Watson Laboratories)	SS	Watson Laboratories		UNK	
			Methadone	SS				
			Quetiapine	SS				
			Ethanol	SS				

Date:02/04/09ISR Number: 6065408-XReport Type:Expedited (15-DaCompany Report #US-WATSON-2009-00573 Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death		Naproxen Sodium Extended Release (Watson Laboratories)	PS	Watson Laboratories		unknown	
			Clonazepam (Watson Laboratories)	SS	Watson Laboratories		UNK	
			Tramadol Hydrochloride (Watson Laboratories)	SS	Watson Laboratories		UNK	
			Carisoprodol (Watson Laboratories)	SS	Watson Laboratories		UNK	
			Trazodone Hydrochloride (Watson Laboratories)	SS	Watson Laboratories		UNK	
			Acetaminophen W/Opioid	SS				
			Quetiapine	SS				
			Duloxetine	SS				
			Fexofenadine	SS				
			Thyroid Preparations	SS				
			Ethanol	SS				

Date:02/04/09ISR Number: 6065477-7Report Type:Expedited (15-DaCompany Report #US-WATSON-2009-00683 Age:51 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest		Buspirone Hydrochloride (Watson Laboratories)	PS	Watson Laboratories		unknown	

Advair C

Date:02/05/09ISR Number: 6066774-1Report Type:Expedited (15-DaCompany Report #PT-ASTRAZENECA-2009AC00463 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Coordination Abnormal		Seroquel Sr	PS		ORAL		3 DAY
	Diplopia		Olanzapine	C				18 DAY
	Dysphagia		Olanzapine	C				
	Hypokinesia		Diazepam	C				
	Muscle Rigidity		Biperiden	C				
	Salivary Hypersecretion		Haldol	C				
	Somnolence		Haldol	C				
	Speech Di order		Valproate Sodium + Valproic Acid	C				
			Lithium	C				

Date:02/05/09ISR Number: 6066803-5Report Type:Expedited (15-DaCompany Report #US-WATSON-2009-00663 Age:37 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest		Baclofen (Watson Laboratories)	PS	Watson Laboratories		unknown	
			Clonazepam (Watson Laboratories)	SS	Watson Laboratories		UNK	
			Zolpidem Tartrate (Watson Laboratories)	SS	Watson Laboratories		UNK	
			Bupropion Hydrochloride Xl (Watson Laboratories)	SS	Watson Laboratories		UNK	
			Promethazine (Watson Laboratories)	SS	Watson Laboratories		UNK	
			Quetiapine	SS				
			Methadone	SS				
			Duloxetine	SS				
			Lithium	SS				
			Levothyroxine	SS				
			Lamotrigine	SS				
			Efavirenz	SS				
			Emtricitabine W/Tenofovir	SS				

Date:02/05/09ISR Number: 6066848-5Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2008UW25366 Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Senile Dementia		Seroquel	PS		ORAL		40 MON
			Seroquel	SS		ORAL		40 MON

Date:02/05/09ISR Number: 6066852-7Report Type:Expedited (15-DaCompany Report #US-JNJFOC-20060402001 Age: Gender:Male I/FU:I

Outcome
Hospitalization - Initial or Prolonged

Date:02/05/09ISR Number: 6067601-9Report Type:Expedited (15-DaCompany Report #US-WATSON-2009-00675 Age:47 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death		Gabapentin (Watson Laboratories)	PS	Watson Laboratories		unknown	
			Bupropion Hydrochloride Xl (Watson Laboratories)	SS	Watson Laboratories		UNK	
			Quetiapine	SS				

Date:02/05/09ISR Number: 6067613-5Report Type:Expedited (15-DaCompany Report #US-WATSON-2009-00622 Age:55 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest		Ibuprofen (Watson Laboratories)	PS	Watson Laboratories		unknown	
			Hydrocodone Bitartrate/Acetaminophen Unknown Strength (Watson)	SS	Watson Laboratories		UNK	
			Bupropion Hydrochloride Xl (Watson Laboratories)	SS	Watson Laboratories		UNK	
			Aspirin /00002701/	SS				
			Quetiapine	SS				

Date:02/05/09ISR Number: 6067679-2Report Type:Expedited (15-DaCompany Report #US-WATSON-2009-00814 Age:22 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest		Alprazolam (Watson Laboratories)	PS	Watson Laboratories		unknown	
			Heroin	SS				
			Methadone	SS				
			Quetiapine	SS				

Date:02/05/09ISR Number: 6067681-0Report Type:Expedited (15-DaCompany Report #US-WATSON-2009-00818 Age:32 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardio-Respiratory Arrest		Sertraline Hydrochloride (Watson Laboratories)	PS	Watson Laboratories		unknown	
			Diphenhydramine (Watson Laboratories)	SS	Watson Laboratories		UNK	
			Clonazepam (Watson Laboratories)	SS	Watson Laboratories		UNK	
			Hydrocodone Bitartrate/Acetaminophen Unknown Strength (Watson)	SS	Watson Laboratories		UNK	
			Marijuana	SS			UNK	

Lithium	SS		UNK
Quetiapine	SS		UNK
Methadone	SS		UNK

Date:02/05/09ISR Number: 6067705-0Report Type:Expedited (15-DaCompany Report #US-WATSON-2009-00799 Age:56 YR Gender:Female I/FU:I

Outcome	PT	Report Source
Death	Death	

Product	Role	Manufacturer	Route	Dose	Duration
Ibuprofen (Watson Laboratories)	PS	Watson Laboratories		unknown	
Lorazepam (Watson Laboratories)	SS	Watson Laboratories		UNK	
Quetiapine	SS				
Carbamazepine	SS				
Duloxetine	SS				
Lamotrigine	SS				

Date:02/05/09ISR Number: 6067712-8Report Type:Expedited (15-DaCompany Report #US-WATSON-2009-00804 Age:61 YR Gender:Female I/FU:I

Outcome	PT	Report Source
Death	Cardio-Respiratory Arrest	

Product	Role	Manufacturer	Route	Dose	Duration
Diazepam (Watson Laboratories)	PS	Watson Laboratories		unknown	
Fentanyl Unknown Strength (Watson Laboratories)	SS	Watson Laboratories		UNK	
Quetiapine	SS				
Lithium	SS				
Methadone	SS				

Date:02/05/09ISR Number: 6067715-3Report Type:Expedited (15-DaCompany Report #US-WATSON-2009-00805 Age:66 YR Gender:Female I/FU:I

Outcome	PT	Report Source
Death	Death	

Product	Role	Manufacturer	Route	Dose	Duration
Ibuprofen (Watson Laboratories)	PS	Watson Laboratories		unknown	
Gabapentin (Watson Laboratories)	SS	Watson Laboratories		UNK	
Verapamil (Watson Laboratories)	SS	Watson Laboratories		UNK	
Quetiapine	SS				
Aspirin /00002701/	SS				

Date:02/05/09ISR Number: 6067919-XReport Type:Expedited (15-DaCompany Report #GB-RANBAXY-2009RR-21517 Age:61 YR Gender:Male I/FU:I

Outcome	PT	Report Source
Life-Threatening Hospitalization - Initial or Prolonged	Coma Overdose Suicide Attempt	

Product	Role	Manufacturer	Route	Dose	Duration
Sertraline	PS	Ranbaxy Pharmaceuticals, Inc.	ORAL	3.1 g, UNK 4.3 g, UNK	
Quetiapine	SS				
Benzodiazepine	C				
Paracetamol	C				

ORAL)

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Myocardial Infarction		Seroquel	PS		ORAL		
Life-Threatening			Seroquel	SS		ORAL		
			Namenda	C				3 DAY

Date:02/11/09ISR Number: 6073047-XReport Type:Expedited (15-DaCompany Report #US-BRISTOL-MYERS SQUIBB COMPANY-14475248 Age:54 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Creatine Phosphokinase Increased		Abilify Tabs 10 Mg	PS				
	Blood Sodium Increased		Seroquel	SS			every night	
	Delirium		Xanax	SS				
	Hyperreflexia		Lithium	SS				
	Hyperthermia		Prozac	SS			1 Dosage form= 40 (Units not specified)	
	Liver Function Test Abnormal							
	Mental Status Changes		Ambien	SS				
	Tremor							
	White Blood Cell Count Increased							

Date:02/11/09ISR Number: 6073163-2Report Type:Expedited (15-DaCompany Report #BR-ASTRAZENECA-2009UW03612 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death		Seroquel	PS		ORAL		

Date:02/11/09ISR Number: 6073165-6Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2009UW03792 Age:9889 DY Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Therapeutic Agent Toxicity		Seroquel	PS		ORAL		8 YR
			Seroquel	SS		ORAL		8 YR

Date:02/11/09ISR Number: 6073173-5Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2009UW03625 Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Fall		Seroquel	PS		ORAL		
	Hospitalisation							
	Lower Limb Fracture							

Date:02/11/09ISR Number: 6073202-9Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2009UW01411 Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Overdose		Seroquel	PS		ORAL		
			Methadone	SS				

Other

Product	Role	Manufacturer	Route	Dose	Duration
Temesta /00273201/ (Temesta Lorazepam) (Not Specified)	PS		ORAL	(2 MG QD ORAL)	
Seroquel /01270901/ (Seroquel Quetiapine) (Not Specified)	SS		ORAL	(300 MG QD ORAL)	

Date:02/23/09ISR Number: 6093796-7Report Type:Direct Company Report #CTU 367171 Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death		Methadone 10 Mg	PS		ORAL	10 MG 2 DAILY, 2 BED TIM PO	
			Seroquel 300 Mg	SS		ORAL	1,500 MG BED TIME PO	6 YR

Date:02/24/09ISR Number: 6088512-9Report Type:Expedited (15-DaCompany Report #CA-ASTRAZENECA-2009UW00170 Age: Gender: I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Platelet Count Decreased White Blood Cell Count Decreased		Seroquel Novo-Quetiapine	PS SS		ORAL UNKNOWN		5 YR

Date:02/24/09ISR Number: 6088957-7Report Type:Expedited (15-DaCompany Report #AU-ASTRAZENECA-2009AP01373 Age:62 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Neutrophil Count Decreased White Blood Cell Count Decreased		Seroquel Seroquel	PS SS		ORAL ORAL	TAKEN AS WELL AS 50MG TWICE DAILY	

Date:02/24/09ISR Number: 6089032-8Report Type:Expedited (15-DaCompany Report #A0769523A Age:49 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Other	Completed Suicide		Paxil	PS	Glaxosmithkline	ORAL	30MG Twice per day	
			Alcohol	SS	Glaxosmithkline			
			Ativan	SS		ORAL	2MG Twice per day	
			Cyclobenzaprine	SS		ORAL		
			Klonopin	SS		ORAL	2MG As required	
			Metoprolol	SS		ORAL		
			Remeron	SS		ORAL	45MG Per day	
			Seroquel	SS		ORAL	300MG Per day	
			Tramadol	SS		ORAL		

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:02/27/09ISR Number: 6096036-8Report Type:Periodic Company Report #A0742634A Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Interaction		Lamictal	PS	Glaxosmithkline	ORAL		
	Palpitations		Quetiapine	SS				

Date:02/27/09ISR Number: 6096418-4Report Type:Periodic Company Report #A0760260A Age:58 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Interaction		Lamictal	PS	Glaxosmithkline	ORAL		
	Sedation		Ambien	SS		ORAL		
			Seroquel	SS				

Date:02/27/09ISR Number: 6096441-XReport Type:Periodic Company Report #A0761411A Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Rash		Lamictal	PS	Glaxosmithkline	ORAL	100MG Per day	
	Stevens-Johnson Syndrome		Lamotrigine	SS	Glaxosmithkline	ORAL	100MG Per day	
			Seroquel	SS				

Date:02/27/09ISR Number: 6096523-2Report Type:Expedited (15-DaCompany Report #CH-WYE-G03161909 Age:42 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction		Temesta	PS	Wyeth Pharmaceuticals Inc.	ORAL		1 DAY
	Intentional Overdose		Ethanol	C	Unknown			
	Restless Legs Syndrome		Ritalin	C	Ciba-Geigy	ORAL		
			Efexor	I	Wyeth Pharmaceuticals Inc.	ORAL		
			Seroquel	I	Zeneca	ORAL		
			Methadone	I	Unknown	ORAL		

Date:02/27/09ISR Number: 6096617-1Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2009UW05076 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Blood Glucose Increased		Seroquel Xr	PS		ORAL		
	Systemic Lupus Erythematosus							

Date:02/27/09ISR Number: 6096685-7Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2009UW05059 Age:43 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Panic Attack		Seroquel	PS		ORAL		

Date:02/27/09ISR Number: 6101101-2Report Type:Expedited (15-DaCompany Report #PAR_02851_2009 Age:48 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Toxicity	Literature	Diazepam	PS			DF	
	Malaise	Health	Quetiapine	SS			DF	
		Professional	Methadone	SS			DF	
			Dextromethorphan	SS			DF	
			Formethazine	SS			DF	
			Nordiazepam	C				

Date:02/27/09ISR Number: 6104089-3Report Type:Expedited (15-DaCompany Report #1000004856 Age:30 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Asphyxia	Foreign	Escitalopram					
	Completed Suicide	Health	(Escitalopram					
		Professional	Oxalate) (Tablets)	PS			20 MG (20 MG, 1 IN 1 D)	
			Seroquel (200 Milligram, Tablets)	SS		ORAL	600 MG (600 MG, 1 IN 1 D), ORAL	

Date:02/27/09ISR Number: 6105254-1Report Type:Periodic Company Report #RB-2299-2008 Age:34 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Respiratory Depression	Health	Suboxone	PS			8 MG	
Hospitalization - Initial or Prolonged		Professional	Clozapine	SS		ORAL	ORAL	
			Lithium	SS		ORAL	ORAL	
			Cymbalta	SS		ORAL	ORAL	
			Seroquel	SS		ORAL	ORAL	
			Topamax	SS				

Date:02/27/09ISR Number: 6105279-6Report Type:Periodic Company Report #RB-8991-2008 Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Toxicity	Health	Buprenorphine	PS				
		Professional	Nordiazepam	SS				
			Quetiapine	SS				

Date:02/27/09ISR Number: 6107373-2Report Type:Periodic Company Report #RB-0216-2008 Age:36 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Toxicity	Health	Buprenorphine	PS				
		Professional	Methocarbamol	SS				
			Zonisamide	SS				
			Quetiapine	SS				
			Ethanol	SS				

Date:03/02/09ISR Number: 6098661-7Report Type:Expedited (15-DaCompany Report #US-TYCO HEALTHCARE/MALLINCKRODT-T200900337 Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source
Death	Cardio-Respiratory Arrest Completed Suicide	

Product	Role	Manufacturer	Route	Dose	Duration
Oxycodone	PS	Tyco Healthcare	ORAL		
Fluoxetine	SS	Tyco Healthcare	ORAL		
Carisoprodol	SS		ORAL		
Propranolol	SS		ORAL		
Citalopram	SS		ORAL		
Quetiapine	SS				

Date:03/02/09ISR Number: 6098666-6Report Type:Expedited (15-DaCompany Report #US-TYCO HEALTHCARE/MALLINCKRODT-T200900334 Age:39 YR Gender:Female I/FU:I

Outcome	PT	Report Source
Death	Completed Suicide	

Product	Role	Manufacturer	Route	Dose	Duration
Tramadol	PS	Tyco Healthcare	ORAL		
Acetaminophen	SS		ORAL		
Carisoprodol	SS		ORAL		
Quetiapine	SS		ORAL		
Trazodone	SS		ORAL		
Duloxetine	SS		ORAL		
Fexofenadine	SS		ORAL		
Naproxen	SS		ORAL		
Thyroid Preparations	SS		ORAL		
Clonazepam	SS		ORAL		
Ethanol	SS		ORAL		
Opoids	SS				

Date:03/02/09ISR Number: 6098675-7Report Type:Expedited (15-DaCompany Report #US-TYCO HEALTHCARE/MALLINCKRODT-T200900343 Age:40 YR Gender:Female I/FU:I

Outcome	PT	Report Source
Death	Cardio-Respiratory Arrest	

Product	Role	Manufacturer	Route	Dose	Duration
Hydrocodone/Acetaminophen	PS	Tyco Healthcare	ORAL		
Quetiapine	SS		ORAL		
Morphine	SS				

Date:03/02/09ISR Number: 6098704-0Report Type:Expedited (15-DaCompany Report #TR-ASTRAZENECA-2009SE00909 Age: Gender:Male I/FU:I

Outcome	PT	Report Source
Hospitalization - Initial or Prolonged	Drug Eruption	

Product	Role	Manufacturer	Route	Dose	Duration
Seroquel	PS		ORAL	2x1	15 DAY
Depakin	C				

Date:03/02/09ISR Number: 6098733-7Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2009UW05414 Age:49 YR Gender:Female I/FU:I

Outcome	PT	Report Source
Hospitalization - Initial or Prolonged	Loss Of Consciousness	

Product	Role	Manufacturer	Route	Dose	Duration
Seroquel	PS		ORAL		
Methadone	C				
Flexeril	C				
Phenergan	C				
Paxil	C				
Klonopine	C				
Claritin D	C				
Zyrtec	C				
Remeron	C				
Gemfibrozil	C				

Date:03/05/09ISR Number: 6107978-9Report Type:Direct Company Report #CTU 368370 Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dyskinesia		Abilify	PS				
	Tongue Disorder		Seroquel	SS				
			Zoloft	SS				
			Klonopin	SS				

Date:03/05/09ISR Number: 6108662-8Report Type:Expedited (15-DaCompany Report #JPI-P-005723 Age:23 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Pressure Decreased	Foreign	Luvox Ir (Tablets) (Fluvoxamine Maleate)	PS		ORAL	ORAL	
	Coma Scale Abnormal	Health	Quetiapine Fumarate	SS		ORAL	ORAL	
	Depressed Level Of Consciousness	Professional	Brotizolam	SS		ORAL	ORAL	
	Dizziness	Other	Lormetazepam	SS		ORAL	ORAL	
	Drug Toxicity		Flunitrazepam	SS		ORAL	ORAL	
	Multiple Drug Overdose		Triazolam	SS		ORAL	ORAL	
			Clonazepam	SS		ORAL	ORAL	
			Lithium Carbonate	SS		ORAL	ORAL	
			Trazodone Hydrochloride	SS		ORAL	ORAL	
			Carteolol Hydrochloride	C				
			Loxoprofen Sodium	C				

Date:03/05/09ISR Number: 6108691-4Report Type:Expedited (15-DaCompany Report #DSA_33273_2009 Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Drug Interaction	Foreign	Temesta /00273201/ (Temesta - Lorazepam) (Not Specified)	PS		ORAL	25 MG 1X, NOT THE PRESCRIBED AMOUNT, ORAL	
	Intentional Overdose	Health						
	Restless Legs Syndrome	Professional						
		Other	Efexor (/1233802/ (Efexor - Venlafaxine Hydrochloride) (Not Specified)	SS		ORAL	150 MG QD, ORAL	
			Methadone (Methadone)	SS		ORAL	120 MG QD, ORAL	
			Seroquel /01270902/ (Seroquel Quetiapine Fumarate) (Not Specified)	SS		ORAL	200 MG QD, ORAL	
			Ritalin	C				
			Alcohol	C				

Date:03/20/09ISR Number: 6127024-0Report Type:Expedited (15-DaCompany Report #PHHY2009DE08913

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation		Carbamazepine	PS	Novartis Sector: Pharma		600 mg, UNK	
	Antipsychotic Drug Level Below Therapeutic		Risperidone	C			8 mg,/ day	
	Condition Aggravated		Zolpidem	C			10 mg, UNK	
	Drug Interaction		Quetiapine	I			700 mg/d	
	Feeling Abnormal							
	Nervousness							
	Psychotic Disorder							

Date:03/20/09ISR Number: 6128879-6Report Type:Expedited (15-DaCompany Report #14518963

Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Akathisia	Health Professional Company Representative	Emsam	PS			5 MILLIGRAM	
			Abilify	SS				
			Seroquel	SS				

Date:03/23/09ISR Number: 6127448-1Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2009UW06918

Age:82 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypoaesthesia		Seroquel	PS		ORAL	25 MG	
			Synthroid	C				

Date:03/23/09ISR Number: 6127926-5Report Type:Expedited (15-DaCompany Report #CH-ASTRAZENECA-2009PK00859

Age:13 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Leukopenia		Seroquel	PS		ORAL		4 DAY
	Neutropenia		Seroquel	SS		ORAL		3 DAY
			Seroquel	SS		ORAL		7 DAY
			Seroquel	SS		ORAL		37 DAY
			Seroquel	SS		ORAL		90 DAY

Date:03/23/09ISR Number: 6128276-3Report Type:Expedited (15-DaCompany Report #NL-ASTRAZENECA-2009AC00901

Age:18713 DYGender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion		Seroquel	PS		ORAL		
	Drug Interaction		Thyrax Duotab	C		ORAL		
			Simvastatine	C		ORAL		
			Diphantoine-Z	I		ORAL		

Date:03/23/09ISR Number: 6128387-2Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2009UW07221

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death		Seroquel Xr	PS		ORAL		
			Methadone	C				
			Lyrica	C				

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:10/09/09ISR Number: 6395635-3Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2009SE17957 — Age:384 MON Gender:Female — I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death		Seroquel	PS	Zeneca Pharmaceutical	ORAL		

Date:10/09/09ISR Number: 6395758-9Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2009SE17961 — Age: — Gender:Male — I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death		Seroquel Xr	PS	Astrazeneca Pharmaceuticals	ORAL		2 DAY
Other	Overdose		Methadone	SS		UNKNOWN		

Date:10/09/09ISR Number: 6395799-1Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2009UW15018 — Age:5 YR — Gender:Male — I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Agitation		Seroquel Xr	PS		ORAL		
	Anger		Seroquel Xr	SS		ORAL		
	Drug Clearance Increased							
	Drug Effect Decreased							
	Impulse-Control Disorder							
	Initial Insomnia							
	Irritability							

Date:10/12/09ISR Number: 6396222-3Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2009UW10691 — Age:8 YR — Gender:Male — I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Diabetic Coma		Seroquel	PS		ORAL		
Other	Diabetic Ketoacidosis		Abilify	C				
	Type 1 Diabetes Mellitus		Thorazine	C				

Date:10/12/09ISR Number: 6396223-5Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2006UW27948 — Age:540 MON Gender:Male — I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diabetes Mellitus		Seroquel	PS		ORAL	150-300 MG	51 MON
	Diabetes Mellitus		Seroquel	SS		ORAL	150-300 MG	51 MON
	Inadequate Control		Abilify	C			30-60 MG	
	Diabetic Neuropathy		Buspar	C			75-375 MG	
	Type 2 Diabetes Mellitus		Effexor	C				
			Prevacid	C				
			Enalapril	C				
			Lantus	C		SUBCUTANEOUS	86 UNITS AT BEDTIME, 100 UNIT/ML	
			Piroxicam	C				
			Cyclobenzaprine	C				
			Aspirin	C			81 MG, 325 MG	
			Flexeril	C				
			Tylenol	C		ORAL	ONE TO TWO P.O. Q.4 TO 6 HOURS P.R.N., ONE TABLET THREE TIMES A	

	Loperamide Hcl	C	(INHALATION)		
	Hyoscyamine	C	UNKNOWN		
	Byetta	C	UNKNOWN		
	Metformin Hcl	C	UNKNOWN		
	Lyrica	C	UNKNOWN	50MG-100MG	
	Amitriptyline	C	UNKNOWN		
	Diovan	C	UNKNOWN		
	Omeprazole	C	UNKNOWN		
	Avandia	C	UNKNOWN		
	Procrit	C	UNKNOWN		
	Furosemide	C	UNKNOWN		
	Fluconazole	C	UNKNOWN		
	Asa	C	ORAL		
	Geodon	C			4 YR
	Zolpidem	C			

Date:10/29/09ISR Number: 6419356-3Report Type:Expedited (15-DaCompany Report #JP-ASTRAZENECA-2009SE22555 Age:35 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Ketoacidosis		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
			Risperidone	C				

Date:10/29/09ISR Number: 6419379-4Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2009SE22137 Age:23 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide		Seroquel Xr	PS		ORAL		
	Overdose		Depakote	C				

Date:10/29/09ISR Number: 6419576-8Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2009SE21262 Age:21 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsion		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
	Loss Of Consciousness					UNKNOWN		
	Sensory Loss		Lamictal	C		UNKNOWN		
	Tardive Dyskinesia		Depakote	C				
	Weight Increased							

Date:10/29/09ISR Number: 6419961-4Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2009SE22805 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
			Methadone	SS				

Date:10/29/09ISR Number: 6420453-7Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2009SE21569 Age: Gender:Female I/FU:I

Outcome	PT
Hospitalization - Initial or Prolonged	Drug Ineffective
	Dysarthria
	Joint Stiffness

ne	SS		UNKNOWN		
Levonorgestrel	SS		UNKNOWN	2	DAY
Excedrin	SS		UNKNOWN		
Iron	C		UNKNOWN	1	DAY
Supradyn	C		UNKNOWN		
Caffeine	C	Glaxosmithkline	UNKNOWN		

Date:11/06/09ISR Number: 6430719-2Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2009SE23935 Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Large Intestine Perforation		Seroquel	PS	Zeneca Pharmaceutical	ORAL		

Date:11/06/09ISR Number: 6430857-4Report Type:Expedited (15-DaCompany Report #DE-MERCK-0911DEU00008 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Adverse Event		Vytorin	PS	Merck & Co., Inc	ORAL		
	Drug Interaction		Quetiapine Fumarate	SS		ORAL		
	Hospitalisation							
	Rhabdomyolysis							

Date:11/06/09ISR Number: 6430939-7Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2009SE17961 Age:17203 DYGender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Accidental Overdose		Seroquel	PS		ORAL		2 DAY
	Aspiration		Methadone	SS		ORAL		
	Respiratory Arrest		Clonopin	C		ORAL		
			Celexa	C		ORAL		

Date:11/06/09ISR Number: 6431031-8Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2009SE24130 Age: Gender: I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Pancytopenia		Seroquel Xr	PS	Astrazeneca Pharmaceuticals	ORAL		

Date:11/06/09ISR Number: 6431247-0Report Type:Expedited (15-DaCompany Report #US-PFIZER INC-2009290013 Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Altered State Of Consciousness		Geodon	PS	Pfizer, Inc.			
	Aphasia		Seroquel	SS				
	Confusional State							
	Dysarthria							
	Eye Disorder							
	Insomnia							
	Lethargy							
	Somnolence							

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date:01/11/10ISR Number: 6532745-1Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2010SE00908

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide		Quetiapine	PS	Zeneca Pharmaceutical	ORAL		
	Drug Toxicity		Benzodiazepine	SS		ORAL		
			Oxycodone	SS		ORAL		
			Methadone	SS		ORAL		
			Propoxyphene	SS		ORAL		
			Tricyclic Antidepressant	SS		ORAL		
			Varenicline	SS		ORAL		
			Venlafaxine	SS		ORAL		
			Lithium	SS		ORAL		

Date:01/11/10ISR Number: 6532749-9Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2010SE00884

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide		Quetiapine	PS	Zeneca Pharmaceutical	ORAL		
	Drug Toxicity		Lorazepam	SS		ORAL		

Date:01/11/10ISR Number: 6532789-XReport Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2010SE00899

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide		Quetiapine	PS	Zeneca Pharmaceutical	ORAL		
	Drug Toxicity		Charcoal	SS		ORAL		

Date:01/11/10ISR Number: 6532790-6Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2010SE00891

Age:55 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide		Quetiapine	PS	Zeneca Pharmaceutical	ORAL		
	Drug Toxicity		Methadone	SS		ORAL		

Date:01/11/10ISR Number: 6532807-9Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2009SE30536

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Dystonia		Seroquel Xr	PS		ORAL		
			Seroquel Xr	SS		ORAL		
			Seroquel Xr	SS		ORAL		

Date:01/11/10ISR Number: 6532811-0Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2010SE00900

Age:47 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide		Quetiapine	PS	Zeneca Pharmaceutical	ORAL		
	Drug Toxicity		Citalopram	SS		ORAL		
			Warfarin	SS		ORAL		
			Potassium Chloride	SS		ORAL		

Date:01/11/10ISR Number: 6532812-2Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2010SE00879

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest		Quetiapine	PS	Zeneca Pharmaceutical	ORAL		
	Completed Suicide							
	Drug Toxicity		Citalopram	SS		ORAL		
	Respiratory Arrest		Bupropion	SS		ORAL		
			Trazodone	SS		ORAL		

Date:01/11/10ISR Number: 6532842-0Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2010SE00889

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide		Quetiapine	PS	Zeneca Pharmaceutical	ORAL		
	Drug Toxicity		Diazepam	SS		ORAL		
			Temazepam	SS		ORAL		
			Acetaminophen					
			Propoxyphene	SS		ORAL		

Date:01/11/10ISR Number: 6532847-XReport Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2010SE00915

Age:49 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest		Quetiapine	PS	Zeneca Pharmaceutical	ORAL		
	Completed Suicide		Lisinopril	SS		ORAL		
	Drug Toxicity		Beta Blocker	SS		ORAL		
	Respiratory Arrest		Diphenhydramin	SS		ORAL		
			Bupropion	SS		ORAL		
			Topiramate	SS		ORAL		
			Tizanidine	SS		ORAL		
			Mirtazapine	SS		ORAL		
			Tamsulosin	SS		ORAL		
			Cocaine	SS		ORAL		

Date:01/11/10ISR Number: 6532941-3Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2010SE00857

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Completed Suicide		Quetiapine	PS	Zeneca Pharmaceutical	ORAL		
	Drug Toxicity		Lamotrigine	SS		ORAL		
			Acetaminophen					
			Dextromethorphan	SS		ORAL		

Date:01/11/10ISR Number: 6532942-5Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2010SE00746

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest		Quetiapine	PS	Zeneca Pharmaceutical	ORAL		
Hospitalization - Initial or Prolonged	Drug Toxicity		Methadone	SS		ORAL		
	Respiratory Arrest		Benzodiazepine	SS		ORAL		

Date:03/08/10ISR Number: 6617626-7Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2010SE02601 Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Extrapyramidal Disorder		Seroquel Xr	PS		ORAL		
Hospitalization - Initial or Prolonged	Serotonin Syndrome		Cymbalta	SS		ORAL		
			Lithium	SS		UNKNOWN		
			Other Unspecified Medications Described As A Bunch	C				

Date:03/08/10ISR Number: 6617838-2Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2010SE05056 Age:40 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cardiac Arrest		Seroquel	PS		ORAL		
	Hepatic Failure		Seroquel	SS		ORAL		
			Celexa	C				
			Methadone	C		ORAL		

Date:03/08/10ISR Number: 6617960-0Report Type:Expedited (15-DaCompany Report #PHHY2010AR11388 Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Confusional State		Exelon Patch	PS	Novartis Sector: Pharma	TRANSDERMAL	4.6 mg, QD, 1 patch daily 5 cm2	
Other	Decreased Appetite							
	Dizziness							
	Fatigue							
	Gastric Ulcer		Seroquel	SS				
	Hallucination		Diazepam	C				
	Headache							
	Memory Impairment							
	Syncope							
	Weight Decreased							

Date:03/08/10ISR Number: 6617991-0Report Type:Expedited (15-DaCompany Report #JP-ASTRAZENECA-2010SE09372 Age:77 YR Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Coma		Seroquel	PS	Zeneca Pharmaceutical	ORAL		1 DAY
						ORAL		
			Risperdal	C		ORAL		
			Herbesser R	C		ORAL		
			Lasix	C				

Date:03/08/10ISR Number: 6618235-6Report Type:Expedited (15-DaCompany Report #JP-ASTRAZENECA-2010SE08252 Age:23 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Somnolence		Seroquel	PS		ORAL		
	Suicide Attempt		Dogmatyl	SS				
			Toledomin	C				
			Gasmotin	C				
			Bromazepam	C				
			Sepazon	C				

Renal Failure
Sudden Cardiac Death
Surgery

Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Seroquel	PS		ORAL		
	Seroquel	SS		ORAL		
	Norco	C				
	Clonazepam	C		ORAL		19 DAY
	Midodrine	C		ORAL		14 DAY
	Midodrine	C		ORAL		13 DAY
	Levofloxacin	C		INTRAVENOUS		21 DAY
	Zosyn	C		INTRAVENOUS		22 DAY
	Vancomycin	C				7 DAY
	Magnesium Sulfate	C				11 DAY
	Ketorolac	C				1 DAY
	Hydromorphone	C			0.25-0.5 MG PRN	7 DAY
	Heparin	C		SUBCUTANEOUS		4 DAY
	Gabapentin	C		ORAL		5 DAY
	Fentanyl	C				23 DAY
	Epoetin Alfa	C		SUBCONJUNCTIVAL	20000 UNIT	
	Amiodarone	C				26 DAY
	Calcium Acetate	C				7 DAY
	Albuterol	C				
	Famotidine	C				26 DAY
	Dopamine	C			800 MG/250 ML DRIP	
	Dobutamine	C			250 MG/250 ML DRIP	

Date:06/11/10ISR Number: 6765784-6Report Type:Expedited (15-DaCompany Report #IT-ASTRAZENECA-2010SE15651 Age:17965 DYGender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Agitation		Seroquel Xr	PS		ORAL		362 DAY
	Anxiety		Seroquel Xr	SS		ORAL		
	Insomnia		Methadone	C		ORAL		366 DAY
	Withdrawal Syndrome		Tavor	C		ORAL		366 DAY

Date:06/11/10ISR Number: 6765930-4Report Type:Expedited (15-DaCompany Report #JP-BRISTOL-MYERS SQUIBB COMPANY-14754816 Age:37 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Abortion		Abilify Tabs	PS		ORAL	Abilify tabs 6mg	
	Pregnancy		Abilify Tabs	SS		ORAL	Abilify tabs 6mg	
			Abilify Tabs	SS		ORAL	Abilify tabs 6mg	
			Abilify Tabs	SS		ORAL	Abilify tabs 6mg	
			Miradol	SS		ORAL	Tabs	
			Miradol	SS		ORAL	Tabs	
			Miradol	SS		ORAL	Tabs	
			Lullan	SS		ORAL		
			Lullan	SS		ORAL		
			Lullan	SS		ORAL		
			Seroquel	SS		ORAL	Tabs	
			Seroquel	SS		ORAL	Tabs	
			Seroquel	SS		ORAL	Tabs	

			Budeprion Sr	C				

Date:06/18/10ISR Number: 6778805-1Re ort Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2009UW03777 Age:410 MON Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anoxic Encephalopathy		Seroquel	PS		ORAL		6 YR
Other	Coma		Seroquel	SS		ORAL		6 YR
	Diabetes Mellitus		Xanax	C				
	Diabetic Coma		Methadone	C				2 YR
	Lung Disorder		Dilantin	C				
	Nervous System Disorder		Ambien	C				
	Overdose		Duvoid	C				
			Melatonin	C				
			Naprosyn	C		ORAL		

Date:06/18/10ISR Number: 6778806-3Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2007UW12065 Age:19824 DYGender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Blood Cholesterol Increased		Seroquel	PS		ORAL	25MG EVERY MORNING AND 75 MG AT NIGHT FOR 7 DAYS THEN 50	
	Cardiovascular Disorder							
	Neck Injury							
	Type 2 Diabetes Mellitus		Seroquel	SS		ORAL	25MG EVERY MORNING AND 75 MG AT NIGHT FOR 7 DAYS THEN 50	
			Diazepam	C			5 MG AT BEDTIME AS NEEDED	
			Fluoxetine Hcl	C			20-30 MG	
			Fosinopril	C		ORAL	40 MG, 1/2 TABLET EVERY DAY	
			Indomethacin	C		ORAL	25 MG CAPSULE TAKE 1 OR 2 BY MOUTH THREE TIMES A DAY	
			Lansoprazole	C		ORAL		
			Metoprolol	C		ORAL		
			Nifedipine	C		ORAL		
			Simvastatin	C		ORAL	20 MG ONE HALF TABLET EVERY DAY IN EVENING	
			Terazosin Hcl	C		ORAL		
			Terazosin Hcl	C		ORAL		
			Claritin	C				
			Lisinopril	C				
			Venlafaxine	C		ORAL	75 MG AT BEDTIME FOR 7 NIGHTS THEN TAKE ONE TABLET BY	
			Cordarone	C				

Glyburide	C	ORAL	5 MG BEFORE BREAKFAST
Percocet	C	ORAL	5/325 MG TID PRN
Flexeril	C	ORAL	
Celexa	C	ORAL	30-25 MG
Valium	C	ORAL	
Vicodin	C		5/500 MG
Sinequan	C		DISPENSED
Norvasc	C		DISPENSED
		ORAL	

Date:07/09/10ISR Number: 6826689-5Report Type:Expedited (15-DaCompany Report #US-PFIZER INC-2010077521

Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Interaction		Chantix	PS	Pfizer, Inc.	ORAL	0.5 mg, 1x/day	
Other	Overdose		Seroquel	SS			UNK	
	Sleep Disorder		Chantix	I	Pfizer, Inc.		1 mg, UNK	
			Nicotine	I	Pfizer, Inc.		UNK	
			Methadone	I				
			Caffeine	I			UNK	
			Coffee	I			UNK	

Date:07/09/10ISR Number: 6827050-XReport Type:Expedited (15-DaCompany Report #CA-MERCK-1007USA00478

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

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Anxiety		Isentress	PS	Merck & Co	ORAL		
	Depression		Bupropion Hydrochloride	SS		UNKNOWN		
	Drug Interaction		Citalopram	SS		UNKNOWN		
	Paranoia		Clonazepam	SS		UNKNOWN		
	Psychiatric Decompensation		Emtriva	SS		UNKNOWN		
	Psychomotor Skills Impaired		Quetiapine Fumarate	SS		UNKNOWN		
	Suicidal Ideation		Reyataz	SS		UNKNOWN		
	Tearfulness		Risperidone	SS		UNKNOWN		
			Ritonavir	SS		UNKNOWN		
			Tenofovir	SS		UNKNOWN		

Date:07/09/10ISR Number: 6840009-1Report Type:Expedited (15-DaCompany Report #2010SP031964

Age:56 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Accidental Overdose	Study	Peg-Interferon	PS		SUBCUTANEOUS	120 MCG; SC	
Hospitalization - Initial or Prolonged	Incorrect Dose Administered	Health Professional	Ribavirin	SS		ORAL	1000 MG;QD;PO	
	Somnolence		Boceprevir	SS		ORAL	2400 MG;QD;PO;	
	Syncope						2400 MG;QD; PO	
	Toxic Encephalopathy		Seroquel	SS		ORAL	300 MG;HS; PO	
			Ranitidine (Con.)	C				
			Methylin (Con.)	C				
			Cymbalta (Con.)	C				
			Fexofenadine (Con.)	C				
			Zolpidem (Con.)	C				
			Senokot (Con.)	C				

Date:07/16/10ISR Number: 6847435-5Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2008UW20440 Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Death		Seroquel	PS		ORAL	300-600 MG	
	Ill-Defined Disorder		Seroquel	SS		ORAL	300-600 MG	
			Remeron	C				
			Rozerem	C				

Date:07/16/10ISR Number: 6847596-8Report Type:Expedited (15-DaCompany Report #US-PFIZER INC-2010077521 Age: Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Interaction		Chantix	PS	Pfizer, Inc.	ORAL	0.5 mg, 1x/day	
Other	Overdose						UNK	
	Sleep Disorder		Coffee	SS			UNK	
			Seroquel	SS			1 mg, UNK	
			Chantix	I	Pfizer, Inc.			
			Methadone	I			UNK	
			Nicotine	I	Pfizer, Inc.		UNK	
			Caffeine	I				

Date:07/16/10ISR Number: 6847604-4Report Type:Periodic Company Report #US-ASTRAZENECA-2010SE25452 Age:54 YR Gender:Male I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Anaemia		Seroquel	PS		ORAL		7 YR
	Anger		Seroquel	SS		ORAL		
	Antipsychotic Drug Level Increased		Seroquel	SS		ORAL		
	Back Pain		Uroset K	C				
	Blood Glucose Increased		Clonazepam	C			UNKNOWN DOSE TWO TIMES A DAY	
	Drug Dose Omission							
	Intervertebral Disc Disorder		Lithium	C				
	Oropharyngeal Pain		Neurontin	C				
	Prostate Cancer		Avapro	C				
	Somnolence		Allopurinol	C				
	Thyroid Disorder		Flurazepam	C				
	Tooth Disorder		Aspirin	C				
			Percocet	C				
			Percocet	C				
			Promethazine	C				
			Calcium	C				
			Flax Seed Oil	C				
			Antihypertensives	C				

Date:07/16/10ISR Number: 6848407-7Report Type:Expedited (15-DaCompany Report #DE-ASTRAZENECA-2010SE10824 Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Exposure During Pregnancy		Seroquel	PS		ORAL		
	Hypertension							
	Pre-Eclampsia							

Prozac	C
Wellbutrin	C

Date:07/16/10ISR Number: 6848695-7Report Type:Periodic Company Report #US-PFIZER INC-2007075638 Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Interaction		Chantix Tablets	PS	Pfizer, Inc.			
	Nausea		Methadone	I	Pfizer, Inc.			
	Tobacco Withdrawal Symptoms		Prozac	I				
			Prevacid	I				
			Seroquel	I				

Date:07/16/10ISR Number: 6849141-XReport Type:Expedited (15-DaCompany Report #PHHY2010AT45731 Age: Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Interaction		Sandimmun Neoral	PS	Novartis Sector: Pharma			
	Immunosuppressant Drug Level Decreased		Seroquel	I				

Date:07/16/10ISR Number: 6849226-8Report Type:Periodic Company Report #US-PFIZER INC-2007080965 Age: Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Crying		Chantix Tablets	PS	Pfizer, Inc.			
	Drug Interaction		Seroquel	I				
	Headache		Klonopin	I				
	Migraine		Lexapro	I				

Date:07/16/10ISR Number: 6849482-6Report Type:Expedited (15-DaCompany Report #US-ROXANE LABORATORIES, INC.-2010-RO-00858RO Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abnormal Dreams		Methadone	PS	Roxane Laboratories, Inc.			
	Dizziness							
	Drug Interaction		Chantix	SS		ORAL	0.5 mg	
	Fatigue		Chantix	SS		ORAL	1 mg	
	Nightmare		Nicotine	SS				
	Overdose		Caffeine	SS				
	Pruritus		Coffee	SS				
	Sleep Disorder		Seroquel	SS				

Date:07/16/10ISR Number: 6850216-XReport Type:Periodic Company Report #US-PFIZER INC-2007086831 Age: Gender:Female I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Inappropriate Schedule Of Drug Administration		Chantix Tablets	PS	Pfizer, Inc.			
	Nausea		Seroquel	SS				
	Weight Increased		Lasix	C				
			Famotidine	C				
			Lovastatin	C				

Soma	C		
Depakote	C	ORAL	
Effexor	C		75-150mg
Parlodel	C		
Sinemet	C		25-100 and 50-200
Allegra D	C		
Mirapex	C		1-1.5mg
Atrovent	C		0.02 PERCENTAGE
Requip	C		
Mellaril	C		

Date:07/20/10ISR Number: 6859896-6Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2006UW08328 Age:40 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diabetic Neuropathy		Seroquel	PS		ORAL	25-400 MG	59 MON
	Gestational Diabetes		Seroquel	SS		ORAL		1068 DAY
	Type 2 Diabetes Mellitus		Prozac	C		ORAL	20-40 MG	
			Trazodone	C		ORAL	50-300 MG	
			Zyprexa	C			5-10 MG	
			Risperdal	C			2-4 MG	
			Neurontin	C			300-900 MG	
			Albuterol	C			PRN	
			Lovastatin	C				

Date:07/20/10ISR Number: 6859915-7Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2010SE33310 Age:20 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abnormal Dreams		Seroquel	PS	Zeneca Pharmaceutical	ORAL		
Other	Dizziness		Chantix	I		ORAL		
	Drug Interaction		Chantix	I		ORAL		
	Fatigue		Methadone	I		UNKNOWN		
	Nightmare		Nicotine	I		UNKNOWN		
	Overdose		Caffeine	I		UNKNOWN		
	Sleep Disorder							

Date:07/20/10ISR Number: 6860150-7Report Type:Expedited (15-DaCompany Report #CH-WYE-G05451010 Age:30 YR Gender:Female I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Akathisia		Efexor	PS	Wyeth Pharmaceuticals Inc.	ORAL		
Other	Drug Interaction		Risperdal	I	Janssen Pharmaceuticals	ORAL		5 DAY
			Seroquel	I	Astrazeneca	ORAL		22 DAY
			Seroquel	I	Astrazeneca	ORAL		

Date:07/20/10ISR Number: 6861094-7Report Type:Expedited (15-DaCompany Report #DE-ASTRAZENECA-2010SE32949 Age:27 YR Gender:Male I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Aggression		Seroquel Prolong	PS	Astrazeneca Pharmaceuticals	ORAL	25 MG ON FIRST TWO	
	Suicidal Ideation							

Fumarate)				
Formulation Unknown	SS		ORAL	ORAL
Goshajinkigan (Herbal Extract Nos)	C			
Yokukan-San (Herbal Extract Nos)	C			
Lendormin (Brotizolam)	C			
Desyrel (Trazodone Hydrochloride)	C			
Protecadin (Lafutidine)	C			
Alosenn (Achillea Millefolium, Rubia Tinctorum Root Tincture, Senna				
Alexandrina Fruit,	C			
Vitamedin (Benfotiamine)	C			
Rize (Clotiazepam)	C			

Date:07/28/10ISR Number: 6878308-XReport Type:Expedited (15-DaCompany Report #US-PFIZER INC-2010077521 — Age: — Gender:Male — I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Drug Interaction		Chantix	PS	Pfizer, Inc.	ORAL	0.5 mg, 1x/day	
Other	Overdose							
	Sleep Disorder		Coffee	SS			UNK	
			Seroquel	SS			UNK	
			Chantix	I	Pfizer, Inc.		1 mg, UNK	
			Methadone	I				
			Nicotine	I	Pfizer, Inc.		UNK	
			Caffeine	I			UNK	

Date:07/28/10ISR Number: 6878702-7Report Type:Expedited (15-DaCompany Report #B0667249A — Age:48 YR — Gender:Female — I/FU:I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Neuroleptic Malignant Syndrome		Frosinor	PS	Glaxosmithkline	ORAL	400MG per day	143 DAY
			Haloperidol	SS		INTRAVENOUS	5MG per day	1 DAY
			Risperdal	SS		ORAL	6MG per day	
			Seroquel	SS		ORAL	900MG per day	
			Tiaprizal	SS		INTRAVENOUS	100MG per day	

Date:07/28/10ISR Number: 6879258-5Report Type:Expedited (15-DaCompany Report #US-ASTRAZENECA-2008UW03276 — Age:71 YR — Gender:Female — I/FU:F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Fall		Seroquel	PS		ORAL		
	Fatigue		Seroquel	SS		ORAL		
	Insomnia		Lunesta	SS				
	Platelet Count Increased		Lunesta	SS				
	Somnolence		Atenolol	C				
	Weight Increased		Enalapril	C				
	Wrong Technique In Drug Usage Process							