

Integrated Summary Table of Narratives for Death Events Reported to AERS from 1995-2007 Related to Zolpidem Use in Children < 17 years old (n=13)
Zolpidem FDA Approval Date December 16, 1992

AGE	Category	Country	
1 17yo	suicide	US	A 17-year-old male was found dead from an apparent suicide approximately 5 months after initiating zolpidem 5 mg at bedtime for insomnia. Past medical history included anxiety and insomnia (per psychiatrist and psychologist). On the night prior to the suicide (according to a diary and note found with the body), he experienced losing motor control and judgment, dizziness, restlessness, paranoia and hallucinations (bright lights, waves, shadows). It was unclear if he had taken zolpidem that evening, though it was reported that he "routinely took zolpidem to help him sleep". The next morning, his father found his body supine in bed with a plastic bag around his head. There was a bottle of what appeared to be antifreeze next to the bottle. A diary kept by the patient revealed thoughts of suicide (onset unreported) and gender identity disorder. An autopsy revealed congested lungs with recent hemorrhage and liver and kidney congestion; a drug screen showed the presence of caffeine only. This case was reported by an attorney. Report Received 2/12/2007.
2 15yo	suicide	US	A 15-year-old male committed suicide by hanging. He had an 8 month history of depression which included hospitalizations for depression and suicide attempt (he may have been receiving zolpidem at this time, report is unclear). Concomitant medications included paroxetine 20 mg QD (started approximately 20 days prior to his death, dose escalating until time of death), zolpidem 10 mg HS (started 13 days prior), diphenhydramine (started 9 days prior), risperidone 1 mg QD (started approximately 5 days prior). Please note: a duplicate report was received on this death event. Report received 8/27/2002.
3 16yo	cardiomyopathy	US	A 16-year-old female died (circumstances of death unreported). The medical examiner's report stated that the cause of death was cardiac arrhythmia due to ventricular cardiomyopathy. The cardiomyopathy was not previously diagnosed; it was reported that she had a normal EKG 5 years prior to death and "normal blood pressure and pulse". She had received sertraline 50 mg QHS for the treatment of major depressive disorder for approximately one year prior to her death; she had received zolpidem 5 to 10 mg QHS PRN for approximately 6 months prior to her death. Medical history included Asperger's syndrome, major depression, learning disability, and a sleep disorder. No zolpidem was found in the heart blood sample at autopsy. Report received date not known.
4 21d	congenital	France	A 3 week old male baby (GA 39 weeks 5 days, weight unreported) experienced cardiac failure and died. He had been diagnosed with cardiac abnormalities at a 22 week ultrasound; Mongolism was diagnosed at birth. The mother was diagnosed with HIV infection at 4 months of pregnancy. She received treatment with zidovudine, lamivudine, lopinavir, ritonavir, zolpidem, bromazepam, and buprenorphine during her pregnancy (dates of exposure unreported). Down's Syndrome 39 wks gestation born with AV canal with heart failure, thrombocytopenia (myelodysplasia and pre-leukemic state), renal failure with anuria, born in Europe "According to Health Authorities, zolpidem, bromazepam, zidovudine, lamivudine+zidovudine and lopinavir+ritonavir were suspected and their causal role was assessed: "Doubtful". Report received 03/31/2004.
5 2d	congenital	France	A 2-day old female neonate (GA, weight unreported) died of mesenteric infarction. Her mother had taken heptaminol, zolpidem, tianeptine, bromazepam, timebutine, amoxicillin, oxomemazine, guaifenesine, benzoate sodium, and paracetamol sometime (trimester exposure unreported) during her pregnancy. No further information is available. Report received 1/08/1999.
7	congenital	Switzerland	A 36 year old female underwent a therapeutic abortion at approximately 23 weeks of gestation. Ultrasound of the fetus revealed multiple anomalies and malformations including: retrognathia, deformation of the thorax and vertebral column, pterygia at elbows and ankles, and lack of mobility. The patient had received citalopram and chlorprothixene during the first and second trimesters and flurazepam during the first trimester only. Preliminary autopsy results suggest a neurological cause for the deformities (probably medullary neuronal depletion). No further information is available. Report received 8/28/2007.
6 Newborn	neonatal complication	US	A newborn male (GA unreported) was born at home and presented to the ED approximately 1-hour after birth in respiratory arrest; attempts to resuscitate were unsuccessful. The mother was reportedly a chronic substance abuser who took alprazolam throughout her pregnancy. Upon autopsy, the following drugs were detected: alprazolam, diphenhydramine, E7fluoxetine, norfluoxetine, zolpidem and caffeine. No further information is available. Report received 9/26/2007.

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Excluded Cases as outlined in Safety Review (n=6)

AGE	Y	Country	Category	Narrative
8		Switzerland	overdose (chronic use of zolpidem indeterminate)	A 38-year old female patient had been treated with zolpidem (stilnox)10mg/day for insomnia and paroxetine 1 tablet/day for anxio-depressive state for 1 year when she learned she was pregnant. Therapeutic abortion planned due to possible hydrops fetalis. Report received 12/07/2004.
10	14yo	US	overdose (chronic use of zolpidem indeterminate)	A 14-year-old female with a past history of suicide attempts presented to the hospital obtunded after being found with empty bottles of zolpidem, risperidone and fluoxetine. Autopsy revealed massive hepatic necrosis. Cause of death was suicide due to the combined effects of benzodiazepines, fluoxetine (2,500 ng/mL), and zolpidem (200 ng/mL). Please note: a duplicate report was received on this death event. Report received 9/15/2005.
9	3yo	France	accidental ingestion	3-year-old male. This is a report from UCB, a licensing partner of Pfizer for hydroxyzine. A pharmacist reported that a 3-year-old boy was found dead, naked, downstairs of his 5 floors building in Feb2007. An autopsy was performed: traces of drugs (hypnotics, tranquilizers) were found. Drug administration error was suspected. A police investigation was in progress. A search carried out at the mother's residence allowed to find several drug blisters, including Atarax 100 (hydroxyzine hydrochloride - lot nr. 8765). The mother may have stolen drugs at work (she was nursing-auxiliary). It seems however that Atarax was not stolen at the mother's working place because no box of this lot nr. was delivered there. Follow-up (13Sep2007): The pharmacist further reported that the medications found in the mother's home were Lexomil (lot 1495, exp.Nov2007), Stilnox 10mg (lots 5y010 and 6y052, Tranxene 10mg (lot 634, exp Jan2009), 20mg and 50 mg. The boy died on 14Feb2007. The cause of death was the defenestration. The autopsy found traces of hypnotics and tranquilizer. Company Clinical Evaluation. Based on the information provided in the case, this individual report would not seem to modify the risk-benefit profile of the subject drug. Report received 09/27/2007.
11	6yo	France	maternal dosing	6-year-old male death by drowning. History of this child to be autistic, hair analysis at death indicated exposure to Ambien for ~6 months. Possible that the Stepmother administered. Physician suspected Munchausen by proxy. Report received 6/28/2006.
12	4.9	US	maternal dosing	A physician reported a death with a 4.9-year-old male. Death is a possible homicide involving the child's mother. A blood screen detected zolpidem (ambien). Report received 2/27/2001.
13	Newborn	US	heresay	Initial information received via the internet from a consumer regarding a newborn born of respiratory problem and died, ? related to Ambien. A female heard a story about another women (age unspecified) who took zolpidem NOS (Ambien) which caused her baby to be born with respiratory problems and that the child died. Reaction as reported: caused her baby to be born with respiratory problems. No further details included. Report received 4/03/2006.