

aripiprazole to end January 2009

| | | | | Case Group | Death Outcomes | Sole |
|----------------------------|----------------------|--|--|--------------------------|----------------|------|
| Case Count | | | | 198 | 3 | 146 |
| Medicine | Reaction Count | Blood and lymphatic system disorders | Pancytopenia | 1 | 0 | 1 |
| | | | Leukocytosis | 1 | 0 | 0 |
| | | | Neutropenia | 2 | 0 | 2 |
| | | | Blood and lymphatic system disorders | 4 | 0 | 3 |
| | | Cardiac disorders | Conduction disorder | 1 | 0 | 1 |
| | | | Wolff-Parkinson-White syndrome | 1 | 0 | 1 |
| | | | Arrhythmia | 1 | 0 | 1 |
| | | | Bradycardia | 1 | 0 | 1 |
| | | | Tachycardia | 9 | 0 | 2 |
| | | | Sinus tachycardia | 1 | 0 | 1 |
| | | | Supraventricular tachycardia | 1 | 0 | 0 |
| | | | Cardiac arrest | 1 | 0 | 0 |
| | | | Cyanosis | 1 | 0 | 1 |
| | | | Palpitations | 2 | 0 | 1 |
| | | | Dilatation ventricular | 1 | 0 | 0 |
| | | | Ventricular dysfunction | 1 | 0 | 0 |
| | | | Cardiac disorders | 21 | 0 | 9 |
| | | | Congenital, familial and genetic disorders | Heart disease congenital | 1 | 0 |
| | | Congenital cardiovascular anomaly | | 1 | 0 | 1 |
| | | Trisomy 21 | | 1 | 0 | 0 |
| | | Limb malformation | | 1 | 0 | 0 |
| | | Kidney malformation | | 1 | 0 | 0 |
| | | Congenital, familial and genetic disorders | | 5 | 0 | 1 |
| | | Endocrine disorders | Hyperprolactinaemia | 1 | 0 | 0 |
| | | | Inappropriate antidiuretic hormone secretion | 1 | 0 | 1 |
| | | | Endocrine disorders | 2 | 0 | 1 |
| | | Eye disorders | Eye disorder | 1 | 0 | 1 |
| | | | Oculogyric crisis | 3 | 0 | 3 |
| | | | Mydriasis | 1 | 0 | 0 |
| | | | Eye rolling | 2 | 0 | 2 |
| | | | Photopsia | 1 | 0 | 1 |
| | | | Vision blurred | 5 | 0 | 4 |
| | | | Eye disorders | 13 | 0 | 11 |
| Gastrointestinal disorders | Dental caries | 3 | 0 | 3 | | |
| | Pancreatitis | 2 | 0 | 2 | | |
| | Diarrhoea | 3 | 0 | 2 | | |
| | Constipation | 1 | 0 | 0 | | |
| | Dyspepsia | 4 | 0 | 4 | | |
| | Abdominal pain | 2 | 0 | 2 | | |
| | Abdominal pain upper | 1 | 0 | 1 | | |

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|----------|----------------|--|---|---------------------------|----------|-----------|---|
| Medicine | Reaction Count | Gastrointestinal disorders | Abdominal discomfort | 1 | 0 | 1 | |
| | | | Dysphagia | 1 | 0 | 1 | |
| | | | Faecal incontinence | 2 | 0 | 2 | |
| | | | Nausea | 11 | 0 | 10 | |
| | | | Vomiting | 12 | 0 | 12 | |
| | | | Lip swelling | 1 | 0 | 1 | |
| | | | Hypoaesthesia oral | 1 | 0 | 1 | |
| | | | Salivary hypersecretion | 2 | 0 | 2 | |
| | | | Swollen tongue | 2 | 0 | 1 | |
| | | | Tongue oedema | 2 | 0 | 1 | |
| | | | Gastrointestinal disorders | 51 | 0 | 46 | |
| | | General disorders and administration site conditions | Pyrexia | 7 | 0 | 2 | |
| | | | Death | 2 | 1 | 1 | |
| | | | Sudden death | 1 | 1 | 0 | |
| | | | Asthenia | 1 | 0 | 0 | |
| | | | Fatigue | 3 | 0 | 2 | |
| | | | Malaise | 3 | 0 | 3 | |
| | | | Gait disturbance | 6 | 0 | 4 | |
| | | | Condition aggravated | 2 | 0 | 2 | |
| | | | Exercise tolerance decreased | 1 | 0 | 1 | |
| | | | Irritability | 1 | 0 | 1 | |
| | | | Oedema peripheral | 1 | 0 | 1 | |
| | | | Chest pain | 1 | 0 | 1 | |
| | | | Chills | 2 | 0 | 0 | |
| | | | Feeling abnormal | 1 | 0 | 1 | |
| | | | Feeling cold | 1 | 0 | 1 | |
| | | | Feeling hot | 1 | 0 | 1 | |
| | | | Feeling of body temperature change | 1 | 0 | 1 | |
| | | | Thirst decreased | 1 | 0 | 1 | |
| | | | Drug interaction | 3 | 0 | 0 | |
| | | | Drug ineffective | 6 | 0 | 4 | |
| | | | Rebound effect | 1 | 0 | 0 | |
| | | | General disorders and administration site conditions | 46 | 2 | 27 | |
| | | | Hepatobiliary disorders | Hepatic function abnormal | 1 | 0 | 1 |
| | | | | Hepatorenal failure | 1 | 0 | 1 |
| | | Hepatobiliary disorders | | 2 | 0 | 2 | |
| | | Immune system disorders | Hypersensitivity | 1 | 0 | 1 | |
| | | | Immune system disorders | 1 | 0 | 1 | |
| | | Infections and infestations | Cellulitis | 1 | 0 | 0 | |
| | | | Nasopharyngitis | 1 | 0 | 0 | |
| | | | Upper respiratory tract infection | 1 | 0 | 1 | |
| | | | Infections and infestations | 3 | 0 | 1 | |

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|-------------------|----------------|--|--|----------------|------|---|
| Medicine | Reaction Count | Injury, poisoning and procedural complications | Drug exposure during pregnancy | 2 | 0 | 1 |
| | | | Excoriation | 1 | 0 | 1 |
| | | | Fall | 1 | 0 | 0 |
| | | | Drug dispensing error | 1 | 0 | 1 |
| | | | Drug prescribing error | 1 | 0 | 0 |
| | | | Accidental overdose | 1 | 0 | 1 |
| | | | Overdose | 4 | 0 | 4 |
| | | | Injury, poisoning and procedural complications | 11 | 0 | 8 |
| | | Investigations | Echocardiogram abnormal | 1 | 0 | 0 |
| | | | Ejection fraction decreased | 1 | 0 | 0 |
| | | | Electrocardiogram T wave abnormal | 1 | 0 | 1 |
| | | | Blood pressure increased | 3 | 0 | 2 |
| | | | Blood creatine phosphokinase increased | 19 | 1 | 9 |
| | | | Blood amylase increased | 1 | 0 | 0 |
| | | | Full blood count decreased | 1 | 0 | 1 |
| | | | Neutrophil count decreased | 2 | 0 | 1 |
| | | | White blood cell count decreased | 1 | 0 | 0 |
| | | | Alanine aminotransferase increased | 1 | 0 | 1 |
| | | | Liver function test abnormal | 3 | 0 | 2 |
| | | | Blood cholesterol increased | 1 | 0 | 1 |
| | | | Low density lipoprotein increased | 1 | 0 | 1 |
| | | | Oxygen saturation decreased | 1 | 0 | 0 |
| | | | Blood glucose increased | 1 | 0 | 0 |
| | | | Corneal reflex decreased | 1 | 0 | 1 |
| | | | Body temperature increased | 3 | 0 | 2 |
| | | | Weight decreased | 1 | 0 | 1 |
| | | | Weight increased | 2 | 0 | 1 |
| | | | Blood creatine decreased | 1 | 0 | 1 |
| | | | Blood urea decreased | 1 | 0 | 1 |
| | | | Urine output increased | 1 | 0 | 1 |
| | | | Antipsychotic drug level increased | 1 | 1 | 0 |
| | | Drug level increased | 1 | 0 | 0 | |
| | | Blood chloride decreased | 1 | 0 | 1 | |
| | | Investigations | 51 | 2 | 28 | |
| | | Metabolism and nutrition disorders | Tetany | 1 | 0 | 1 |
| | | | Diabetic ketoacidosis | 2 | 0 | 2 |
| Polydipsia | 1 | | 0 | 0 | | |
| Hypokalaemia | 1 | | 0 | 0 | | |
| Hyponatraemia | 1 | | 0 | 1 | | |
| Dehydration | 1 | | 0 | 0 | | |
| Diabetes mellitus | 1 | | 0 | 1 | | |

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| Medicine | Reaction Count | Metabolism and nutrition disorders | Hyperglycaemia | 1 | 0 | 1 | |
| | | | Metabolism and nutrition disorders | 9 | 0 | 6 | |
| | | Musculoskeletal and connective tissue disorders | Arthralgia | 2 | 0 | 2 | |
| | | | Joint stiffness | 1 | 0 | 1 | |
| | | | Myositis | 1 | 0 | 1 | |
| | | | Myalgia | 3 | 0 | 1 | |
| | | | Muscle spasms | 5 | 0 | 5 | |
| | | | Muscle tightness | 2 | 0 | 0 | |
| | | | Muscle twitching | 3 | 0 | 2 | |
| | | | Muscle rigidity | 5 | 0 | 4 | |
| | | | Nuchal rigidity | 2 | 0 | 1 | |
| | | | Torticollis | 1 | 0 | 0 | |
| | | | Muscular weakness | 2 | 0 | 2 | |
| | | | Rhabdomyolysis | 1 | 0 | 0 | |
| | | | Musculoskeletal stiffness | 2 | 0 | 1 | |
| | | | Back pain | 2 | 0 | 2 | |
| | | | Neck pain | 2 | 0 | 2 | |
| | | | Musculoskeletal and connective tissue disorders | 34 | 0 | 24 | |
| | | | Nervous system disorders | Facial palsy | 1 | 0 | 1 |
| | | | | Facial paresis | 1 | 0 | 1 |
| | | | | Headache | 5 | 0 | 5 |
| | | | | Amnesia | 2 | 0 | 1 |
| | | Cognitive disorder | | 1 | 0 | 0 | |
| | | Disturbance in attention | | 1 | 0 | 1 | |
| | | Chorea | | 1 | 0 | 1 | |
| | | Akathisia | | 12 | 0 | 10 | |
| | | Bradykinesia | | 1 | 0 | 1 | |
| | | Dyskinesia | | 9 | 0 | 7 | |
| | | Extrapyramidal disorder | | 7 | 0 | 5 | |
| | | Psychomotor hyperactivity | | 1 | 0 | 1 | |
| | | Tardive dyskinesia | | 4 | 0 | 4 | |
| | | Dystonia | | 9 | 0 | 5 | |
| | | Opisthotonus | | 1 | 0 | 1 | |
| | | Diplegia | | 1 | 0 | 1 | |
| | | Locked-in syndrome | | 1 | 0 | 0 | |
| | | Cogwheel rigidity | | 1 | 0 | 0 | |
| | | Parkinsonism | | 3 | 0 | 2 | |
| | | Tremor | | 8 | 0 | 6 | |
| | | Hyperreflexia | 3 | 0 | 2 | | |
| | | Coordination abnormal | 2 | 0 | 1 | | |
| | | Nystagmus | 1 | 0 | 1 | | |
| | | Consciousness fluctuating | 1 | 0 | 0 | | |

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|-------------------------|----------------|---|--|----------------|------------|----|
| | | Nervous system disorders | Depressed level of consciousness | 1 | 0 | 0 |
| | | | Loss of consciousness | 1 | 0 | 0 |
| | | | Sedation | 1 | 0 | 1 |
| | | | Somnolence | 8 | 0 | 7 |
| | | | Syncope | 1 | 0 | 1 |
| | | | Psychomotor skills impaired | 1 | 0 | 0 |
| | | | Clonus | 1 | 0 | 1 |
| | | | Dizziness | 9 | 0 | 8 |
| | | | Drooling | 2 | 0 | 2 |
| | | | Myoclonus | 2 | 0 | 2 |
| | | | Paraesthesia | 1 | 0 | 0 |
| | | | Dysphasia | 1 | 0 | 1 |
| | | | Incoherent | 1 | 0 | 1 |
| | | | Speech disorder | 2 | 0 | 2 |
| | | | Adrenergic syndrome | 1 | 0 | 0 |
| | | | Hypertonia | 3 | 0 | 3 |
| | | | Neuroleptic malignant syndrome | 18 | 1 | 8 |
| | | | Serotonin syndrome | 1 | 0 | 1 |
| | | | Neuropathy peripheral | 1 | 0 | 1 |
| | | | Grand mal convulsion | 1 | 0 | 1 |
| | | | Convulsion | 4 | 0 | 4 |
| | | | Convulsive threshold lowered | 1 | 0 | 1 |
| | | | Hypersomnia | 1 | 0 | 1 |
| | | Nervous system disorders | 140 | 1 | 103 | |
| | | Pregnancy, puerperium and perinatal conditions | Abortion spontaneous | 1 | 0 | 0 |
| | | | Pregnancy, puerperium and perinatal conditions | 1 | 0 | 0 |
| | | Psychiatric disorders | Agitation | 12 | 1 | 10 |
| | | | Anxiety | 6 | 0 | 4 |
| | | | Nervousness | 1 | 0 | 0 |
| | | | Fear | 1 | 0 | 1 |
| | | | Obsessive thoughts | 1 | 1 | 1 |
| | | | Obsessive-compulsive disorder | 1 | 0 | 1 |
| | | | Restlessness | 6 | 0 | 6 |
| | | | Expressive language disorder | 1 | 0 | 0 |
| | | | Confusional state | 5 | 0 | 3 |
| | | | Disorientation | 2 | 0 | 2 |
| | | | Delirium | 4 | 0 | 0 |
| Depression | 2 | | 0 | 1 | | |
| Feeling of despair | 1 | | 0 | 0 | | |
| Psychomotor retardation | 1 | | 0 | 0 | | |
| Delusion | 1 | 0 | 1 | | | |
| Persecutory delusion | 1 | 0 | 1 | | | |

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|----------|----------------|--|---|----------------|-----------|----------|
| | | Psychiatric disorders | Hallucination | 3 | 0 | 3 |
| | | | Hallucination, auditory | 4 | 0 | 1 |
| | | | Thinking abnormal | 2 | 0 | 2 |
| | | | Hypomania | 1 | 0 | 1 |
| | | | Mania | 7 | 1 | 7 |
| | | | Emotional distress | 1 | 0 | 1 |
| | | | Euphoric mood | 1 | 0 | 1 |
| | | | Mood swings | 1 | 0 | 1 |
| | | | Aggression | 3 | 0 | 3 |
| | | | Paranoia | 5 | 0 | 5 |
| | | | Abnormal behaviour | 1 | 0 | 1 |
| | | | Mental status changes | 1 | 0 | 0 |
| | | | Intentional drug misuse | 1 | 0 | 1 |
| | | | Withdrawal syndrome | 3 | 0 | 2 |
| | | | Psychotic disorder | 7 | 0 | 4 |
| | | | Schizophrenia | 1 | 0 | 1 |
| | | | Disturbance in sexual arousal | 1 | 0 | 1 |
| | | | Insomnia | 7 | 0 | 5 |
| | | | Abnormal sleep-related event | 1 | 0 | 1 |
| | | | Somnambulism | 1 | 0 | 1 |
| | | | Sleep disorder | 3 | 0 | 3 |
| | | | Intentional self-injury | 2 | 0 | 2 |
| | | | Suicidal ideation | 2 | 1 | 1 |
| | | Psychiatric disorders | 105 | 4 | 79 | |
| | | Renal and urinary disorders | Renal failure acute | 1 | 0 | 0 |
| | | | Dysuria | 2 | 0 | 1 |
| | | | Pollakiuria | 1 | 0 | 1 |
| | | | Urinary incontinence | 3 | 0 | 2 |
| | | | Urinary retention | 2 | 0 | 0 |
| | | | Renal and urinary disorders | 9 | 0 | 4 |
| | | Reproductive system and breast disorders | Galactorrhoea | 1 | 0 | 1 |
| | | | Amenorrhoea | 1 | 0 | 1 |
| | | | Menorrhagia | 1 | 0 | 0 |
| | | | Ejaculation failure | 2 | 0 | 0 |
| | | | Erectile dysfunction | 3 | 0 | 3 |
| | | | Priapism | 1 | 0 | 1 |
| | | | Reproductive system and breast disorders | 9 | 0 | 6 |
| | | Respiratory, thoracic and mediastinal disorders | Pulmonary embolism | 1 | 1 | 0 |
| | | | Dyspnoea | 3 | 0 | 2 |
| | | | Hiccups | 2 | 0 | 2 |
| | | | Rhinorrhoea | 1 | 0 | 1 |
| | | | Laryngospasm | 1 | 0 | 0 |

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|----------|----------------|--|--|----------------|------------|----|
| | | Respiratory, thoracic and mediastinal disorders | Respiratory, thoracic and mediastinal disorders | 8 | 1 | 5 |
| | | Skin and subcutaneous tissue disorders | Blister | 1 | 0 | 1 |
| | | | Erythema | 1 | 0 | 1 |
| | | | Rash papular | 1 | 0 | 1 |
| | | | Pruritus | 3 | 0 | 3 |
| | | | Rash pruritic | 1 | 0 | 1 |
| | | | Psoriasis | 1 | 0 | 1 |
| | | | Rash | 3 | 0 | 3 |
| | | | Hyperhidrosis | 7 | 0 | 3 |
| | | | Night sweats | 1 | 0 | 0 |
| | | | Skin and subcutaneous tissue disorders | 19 | 0 | 14 |
| | | Social circumstances | Promiscuity | 2 | 0 | 2 |
| | | | Bedridden | 1 | 0 | 1 |
| | | | Treatment noncompliance | 1 | 0 | 1 |
| | | | Social circumstances | 4 | 0 | 4 |
| | | Surgical and medical procedures | Therapy regimen changed | 7 | 0 | 5 |
| | | | Surgical and medical procedures | 7 | 0 | 5 |
| | | Vascular disorders | Circulatory collapse | 1 | 0 | 1 |
| | | | Hypotension | 4 | 0 | 1 |
| | | | Orthostatic hypotension | 2 | 0 | 2 |
| | | | Deep vein thrombosis | 1 | 0 | 1 |
| | | | Pallor | 1 | 0 | 0 |
| | | | Hypertension | 3 | 0 | 3 |
| | | | Vascular disorders | 12 | 0 | 8 |
| | | Reaction | 567 | 10 | 396 | |