

Medicine summary - imipramine (to end January 2009)

| | | | Case Group | Death Outcomes | Sole |
|--|--|---|------------|----------------|-----------|
| Case Count | | | 407 | 6 | 231 |
| Reaction Count | Blood and lymphatic system disorders | Anaemia | 3 | 0 | 1 |
| | | Aplastic anaemia | 2 | 1 | 0 |
| | | Bone marrow failure | 1 | 0 | 0 |
| | | Hypoplastic anaemia | 1 | 0 | 0 |
| | | Thrombocytopenia | 6 | 0 | 2 |
| | | Lymphadenopathy | 1 | 0 | 1 |
| | | Leukopenia | 5 | 0 | 3 |
| | | Lymphopenia | 1 | 0 | 1 |
| | | Agranulocytosis | 5 | 0 | 3 |
| | | Neutropenia | 6 | 0 | 4 |
| | | Blood and lymphatic system disorders | | 31 | 1 |
| | Cardiac disorders | Atrioventricular block | 1 | 0 | 1 |
| | | Bundle branch block | 1 | 0 | 0 |
| | | Arrhythmia | 4 | 0 | 2 |
| | | Extrasystoles | 4 | 0 | 1 |
| | | Tachycardia | 6 | 1 | 2 |
| | | Torsade de pointes | 1 | 0 | 0 |
| | | Palpitations | 6 | 0 | 4 |
| | | Cardiac disorders | | 23 | 1 |
| | Congenital, familial and genetic disorders | Cleft lip | 1 | 0 | 1 |
| | | Dysmorphism | 1 | 0 | 1 |
| | | Congenital brain damage | 3 | 0 | 3 |
| | | Congenital, familial and genetic disorders | | 5 | 0 |
| | Ear and labyrinth disorders | Tinnitus | 4 | 0 | 3 |
| | | Vertigo | 3 | 0 | 1 |
| | | Ear and labyrinth disorders | | 7 | 0 |
| | Endocrine disorders | Adrenal insufficiency | 1 | 1 | 0 |
| Inappropriate antidiuretic hormone secretion | | 4 | 0 | 2 | |
| Endocrine disorders | | 5 | 1 | 2 | |
| Eye disorders | Eye pain | 1 | 0 | 0 | |
| | Glaucoma | 1 | 0 | 1 | |
| | Conjunctivitis | 1 | 0 | 1 | |
| | Mydriasis | 2 | 0 | 1 | |
| | Pupillary reflex impaired | 1 | 0 | 0 | |
| | Diplopia | 1 | 0 | 1 | |
| | Vision blurred | 1 | 0 | 0 | |
| | Visual impairment | 8 | 0 | 5 | |
| | Scotoma | 1 | 0 | 1 | |
| | Eye disorders | | 17 | 0 | 10 |
| Gastrointestinal disorders | Pancreatitis | 1 | 0 | 1 | |
| | Reflux oesophagitis | 1 | 0 | 0 | |

Medicine summary - imipramine (to end January 2009)

| | | | Case Group | Death Outcomes | Sole | |
|---------------------------|--|----------------------------|---|-----------------------|----------|-----------|
| Reaction Count | Gastrointestinal disorders | Diarrhoea | 3 | 0 | 2 | |
| | | Constipation | 11 | 0 | 8 | |
| | | Dyspepsia | 2 | 0 | 2 | |
| | | Flatulence | 1 | 0 | 1 | |
| | | Abdominal pain | 9 | 0 | 7 | |
| | | Dysphagia | 1 | 0 | 0 | |
| | | Nausea | 25 | 0 | 14 | |
| | | Vomiting | 18 | 1 | 9 | |
| | | Duodenal ulcer haemorrhage | 2 | 0 | 0 | |
| | | Duodenal ulcer perforation | 1 | 1 | 0 | |
| | | Peptic ulcer perforation | 1 | 1 | 0 | |
| | | Cheilitis | 2 | 0 | 1 | |
| | | Mouth ulceration | 5 | 0 | 4 | |
| | | Stomatitis | 2 | 0 | 2 | |
| | | Peritonitis | 1 | 1 | 0 | |
| | | Dry mouth | 11 | 0 | 8 | |
| | | Salivary hypersecretion | 1 | 0 | 0 | |
| | | Glossitis | 3 | 0 | 2 | |
| | | Tongue ulceration | 2 | 0 | 1 | |
| | | | Gastrointestinal disorders | 103 | 4 | 62 |
| Reaction Count | General disorders and administration site conditions | Pyrexia | 7 | 0 | 3 | |
| | | Sudden death | 1 | 1 | 0 | |
| | | Asthenia | 1 | 0 | 0 | |
| | | Fatigue | 8 | 0 | 4 | |
| | | Malaise | 2 | 0 | 0 | |
| | | Gait disturbance | 2 | 0 | 1 | |
| | | Influenza like illness | 1 | 0 | 1 | |
| | | Irritability | 1 | 0 | 1 | |
| | | Face oedema | 5 | 0 | 4 | |
| | | Oedema | 2 | 0 | 2 | |
| | | Oedema peripheral | 2 | 0 | 1 | |
| | | Chest pain | 2 | 0 | 1 | |
| | | Pain | 1 | 0 | 1 | |
| | | Drug ineffective | 4 | 0 | 2 | |
| | | | General disorders and administration site conditions | 39 | 1 | 21 |
| | | Reaction Count | Hepatobiliary disorders | Hepatitis cholestatic | 4 | 0 |
| Jaundice | 8 | | | 0 | 6 | |
| Hepatic function abnormal | 14 | | | 0 | 5 | |
| Hepatitis | 11 | | | 0 | 6 | |
| | Hepatobiliary disorders | | | 37 | 0 | 20 |
| Reaction Count | Infections and infestations | Candidiasis | 2 | 0 | 0 | |

Medicine summary - imipramine (to end January 2009)

| | | | Case Group | Death Outcomes | Sole |
|----------------|---|--|------------|----------------|----------|
| Reaction Count | Infections and infestations | Oesophageal candidiasis | 1 | 0 | 0 |
| | | Otitis externa | 1 | 0 | 0 |
| | | Pneumonia | 1 | 1 | 0 |
| | | Rash pustular | 1 | 0 | 1 |
| | | Pharyngitis | 3 | 0 | 1 |
| | | Rhinitis | 1 | 0 | 1 |
| | | Infections and infestations | 10 | 1 | 3 |
| | Injury, poisoning and procedural complications | Medication error | 1 | 0 | 1 |
| | | Accidental overdose | 1 | 0 | 1 |
| | | Injury, poisoning and procedural complications | 2 | 0 | 2 |
| | Investigations | Electrocardiogram QT interval | 1 | 0 | 1 |
| | | Electrocardiogram ST segment abnormal | 1 | 0 | 1 |
| | | Electrocardiogram abnormal | 2 | 0 | 2 |
| | | Heart rate increased | 1 | 0 | 0 |
| | | Weight decreased | 3 | 0 | 2 |
| | | Weight increased | 2 | 0 | 1 |
| | | Urine analysis abnormal | 1 | 0 | 0 |
| | | Drug level decreased | 1 | 0 | 0 |
| | | Investigations | 12 | 0 | 7 |
| | Metabolism and nutrition disorders | Decreased appetite | 7 | 0 | 5 |
| | | Increased appetite | 2 | 0 | 2 |
| | | Hyperkalaemia | 2 | 1 | 0 |
| | | Hyponatraemia | 10 | 0 | 3 |
| | | Dehydration | 4 | 0 | 2 |
| | Metabolism and nutrition disorders | 25 | 1 | 12 | |
| | Musculoskeletal and connective tissue disorders | Bone pain | 1 | 0 | 0 |
| | | Osteoporosis | 1 | 0 | 0 |
| | | Systemic lupus erythematosus | 1 | 0 | 0 |
| | | Pathological fracture | 1 | 0 | 0 |
| | | Arthralgia | 2 | 0 | 2 |
| | | Myalgia | 4 | 0 | 3 |
| | | Muscle spasms | 1 | 0 | 0 |
| | | Muscle tightness | 1 | 0 | 1 |
| | | Muscle twitching | 3 | 0 | 2 |
| | | Muscular weakness | 1 | 0 | 1 |
| | | Musculoskeletal and connective tissue disorders | 16 | 0 | 9 |
| | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | Leukaemia granulocytic | 1 | 0 | 0 |
| | | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 | 0 | 0 |
| | Nervous system disorders | Facial palsy | 1 | 0 | 1 |
| | | Parosmia | 1 | 0 | 1 |

Medicine summary - imipramine (to end January 2009)

| | | | Case Group | Death Outcomes | Sole | |
|----------------|--------------------------|---------------------------------|-------------------|----------------|----------|-----------|
| Reaction Count | Nervous system disorders | Encephalopathy | 1 | 0 | 0 | |
| | | Headache | 14 | 0 | 6 | |
| | | Amnesia | 1 | 0 | 1 | |
| | | Memory impairment | 1 | 0 | 0 | |
| | | Extrapyramidal disorder | 5 | 0 | 1 | |
| | | Hyperkinesia | 2 | 0 | 0 | |
| | | Hypokinesia | 1 | 0 | 0 | |
| | | Tardive dyskinesia | 5 | 0 | 1 | |
| | | Dystonia | 4 | 0 | 1 | |
| | | Tremor | 9 | 0 | 6 | |
| | | Ataxia | 6 | 0 | 3 | |
| | | Coordination abnormal | 2 | 0 | 0 | |
| | | Coma | 1 | 0 | 0 | |
| | | Aphasia | 1 | 0 | 1 | |
| | | Somnolence | 8 | 0 | 6 | |
| | | Stupor | 1 | 0 | 0 | |
| | | Syncope | 6 | 1 | 4 | |
| | | Dizziness | 22 | 0 | 8 | |
| | | Hyperaesthesia | 1 | 0 | 1 | |
| | | Paraesthesia | 8 | 0 | 5 | |
| | | Dysgeusia | 1 | 0 | 0 | |
| | | Neuralgia | 1 | 0 | 1 | |
| | | Restless legs syndrome | 1 | 0 | 1 | |
| | | Dysarthria | 2 | 0 | 1 | |
| | | Speech disorder | 3 | 0 | 1 | |
| | | Anticholinergic syndrome | 1 | 0 | 1 | |
| | | Autonomic neuropathy | 1 | 0 | 0 | |
| | | Hypertonia | 2 | 0 | 0 | |
| | | Serotonin syndrome | 2 | 0 | 0 | |
| | | Neuritis | 1 | 0 | 0 | |
| | | Neuropathy peripheral | 2 | 0 | 1 | |
| | | Grand mal convulsion | 2 | 0 | 0 | |
| | Convulsion | 1 | 0 | 1 | | |
| | | Nervous system disorders | | 121 | 1 | 53 |
| | | Psychiatric disorders | Agitation | 10 | 0 | 4 |
| | | | Anxiety | 3 | 0 | 2 |
| | | | Nervousness | 2 | 0 | 2 |
| | | | Neurosis | 1 | 0 | 1 |
| | | | Confusional state | 19 | 1 | 3 |
| | | | Disorientation | 1 | 0 | 0 |
| | | | Delirium | 4 | 0 | 1 |
| | | | Depression | 5 | 0 | 5 |

Medicine summary - imipramine (to end January 2009)

| | | | Case Group | Death Outcomes | Sole | |
|----------------|-----------------------|---|---|----------------|----------|-----------|
| Reaction Count | Psychiatric disorders | Depersonalisation | 6 | 0 | 6 | |
| | | Delusion | 2 | 0 | 0 | |
| | | Hallucination | 15 | 0 | 4 | |
| | | Thinking abnormal | 2 | 0 | 2 | |
| | | Affect lability | 3 | 0 | 3 | |
| | | Emotional distress | 1 | 0 | 0 | |
| | | Euphoric mood | 1 | 0 | 1 | |
| | | Apathy | 1 | 0 | 0 | |
| | | Aggression | 7 | 0 | 6 | |
| | | Personality disorder | 4 | 0 | 4 | |
| | | Drug dependence | 1 | 0 | 0 | |
| | | Withdrawal syndrome | 5 | 0 | 4 | |
| | | Psychotic disorder | 1 | 0 | 0 | |
| | | Libido decreased | 2 | 0 | 2 | |
| | | Insomnia | 8 | 0 | 8 | |
| | | Nightmare | 7 | 0 | 5 | |
| | | Somnambulism | 1 | 0 | 0 | |
| | | Sleep disorder | 2 | 0 | 1 | |
| | | | Psychiatric disorders | 114 | 1 | 64 |
| | | Renal and urinary disorders | Oliguria | 1 | 1 | 0 |
| | | | Renal failure acute | 2 | 1 | 1 |
| | | | Urethral disorder | 1 | 0 | 0 |
| | | | Dysuria | 5 | 1 | 3 |
| | | | Micturition disorder | 4 | 0 | 4 |
| | | | Pollakiuria | 1 | 0 | 1 |
| | | | Urinary incontinence | 2 | 0 | 0 |
| | | | Urinary retention | 7 | 0 | 4 |
| | | | Renal and urinary disorders | 23 | 3 | 13 |
| | | Reproductive system and breast disorders | Gynaecomastia | 3 | 0 | 2 |
| | | | Breast pain | 2 | 0 | 2 |
| | | | Galactorrhoea | 4 | 0 | 2 |
| | | | Suppressed lactation | 1 | 0 | 1 |
| | | | Menstrual disorder | 1 | 0 | 1 |
| | | | Genital ulceration | 1 | 0 | 0 |
| | | | Genital discharge | 1 | 0 | 1 |
| | | | Oedema genital | 1 | 0 | 1 |
| | | | Erectile dysfunction | 1 | 0 | 1 |
| | | | Infertility male | 1 | 0 | 1 |
| | | | Testicular disorder | 2 | 0 | 2 |
| | | | Reproductive system and breast disorders | 18 | 0 | 14 |
| | | Respiratory, thoracic and mediastinal disorders | Dyspnoea | 3 | 0 | 0 |
| | | | Respiratory distress | 1 | 0 | 0 |

Medicine summary - imipramine (to end January 2009)

| | | | Case Group | Death Outcomes | Sole | |
|----------------|---|--|------------|----------------|-----------|------------|
| Reaction Count | Respiratory, thoracic and mediastinal disorders | Cough | 3 | 0 | 1 | |
| | | Respiratory failure | 1 | 1 | 0 | |
| | | Respiratory disorder | 1 | 0 | 0 | |
| | | Dysphonia | 1 | 0 | 1 | |
| | | Epistaxis | 2 | 0 | 1 | |
| | | Respiratory, thoracic and mediastinal disorders | 12 | 1 | 3 | |
| | Skin and subcutaneous tissue disorders | Angioedema | 2 | 0 | 0 | |
| | | Periorbital oedema | 2 | 0 | 2 | |
| | | Urticaria | 8 | 0 | 6 | |
| | | Skin discolouration | 1 | 0 | 1 | |
| | | Dermatitis | 1 | 0 | 1 | |
| | | Rash erythematous | 9 | 0 | 5 | |
| | | Dermatitis exfoliative | 2 | 0 | 2 | |
| | | Skin exfoliation | 1 | 0 | 1 | |
| | | Photosensitivity reaction | 6 | 0 | 4 | |
| | | Pruritus | 25 | 0 | 19 | |
| | | Psoriasis | 1 | 0 | 0 | |
| | | Rash | 21 | 0 | 10 | |
| | | Rash maculo-papular | 21 | 0 | 19 | |
| | | Rash morbilliform | 3 | 0 | 2 | |
| | | Vitiligo | 1 | 0 | 1 | |
| | | Alopecia | 3 | 0 | 2 | |
| | | Cold sweat | 2 | 0 | 1 | |
| | | Hyperhidrosis | 29 | 0 | 17 | |
| | | Nail disorder | 1 | 0 | 0 | |
| | | Purpura | 5 | 0 | 3 | |
| | | Skin and subcutaneous tissue disorders | 144 | 0 | 96 | |
| | Surgical and medical procedures | Therapy regimen changed | 2 | 0 | 0 | |
| | | Surgical and medical procedures | 2 | 0 | 0 | |
| | Vascular disorders | Peripheral ischaemia | 2 | 0 | 1 | |
| | | Hypotension | 12 | 0 | 4 | |
| | | Orthostatic hypotension | 21 | 0 | 10 | |
| | | Thrombosis | 1 | 1 | 0 | |
| | | Thrombophlebitis | 1 | 0 | 0 | |
| | | Vein pain | 1 | 0 | 1 | |
| | | Hot flush | 5 | 0 | 5 | |
| | | Hypertension | 3 | 1 | 1 | |
| | | Vascular disorders | 46 | 2 | 22 | |
| | Reaction | | | 813 | 18 | 447 |