

## **Medicine summary - imipramine (to end January 2009)**

|  |  |   | Case Group | Death Outcomes | Sole       |
|--|--|---|------------|----------------|------------|
| Case Count                                 |  |   | <b>407</b> | <b>6</b>       | <b>231</b> |
| 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          |
|  |  | <b>Blood and lymphatic system disorders</b>       | <b>31</b>  | <b>1</b>       | <b>15</b>  |
| Cardiac disorders                          | 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          |
|  |  | <b>Cardiac disorders</b>                          | <b>23</b>  | <b>1</b>       | <b>10</b>  |
| Congenital, familial and genetic disorders | Congenital, familial and genetic disorders | Cleft lip   | 1          | 0              | 1          |
|  |  | Dysmorphism                                       | 1          | 0              | 1          |
|  |  | Congenital brain damage                           | 3          | 0              | 3          |
|  |  | <b>Congenital, familial and genetic disorders</b> | <b>5</b>   | <b>0</b>       | <b>5</b>   |
| Ear and labyrinth disorders                | Ear and labyrinth disorders                | Tinnitus  | 4          | 0              | 3          |
|  |  | Vertigo   | 3          | 0              | 1          |
|  |  | <b>Ear and labyrinth disorders</b>                | <b>7</b>   | <b>0</b>       | <b>4</b>   |
| Endocrine disorders                        | Endocrine disorders                        | Adrenal insufficiency                             | 1          | 1              | 0          |
|  |  | Inappropriate antidiuretic hormone secretion      | 4          | 0              | 2          |
|  |  | <b>Endocrine disorders</b>                        | <b>5</b>   | <b>1</b>       | <b>2</b>   |
| Eye disorders                              | 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          |
|  |  | <b>Eye disorders</b>                              | <b>17</b>  | <b>0</b>       | <b>10</b>  |
| Gastrointestinal disorders                 | Gastrointestinal disorders                 | Pancreatitis                                      | 1          | 0              | 1          |
|  |  | Reflux oesophagitis                               | 1          | 0              | 0          |

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|                | 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         |
|                |  | <b>Gastrointestinal disorders</b>                           | <b>103</b> | <b>4</b>       | <b>62</b> |
|                | 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         |
|                |  | <b>General disorders and administration site conditions</b> | <b>39</b>  | <b>1</b>       | <b>21</b> |
|                | Hepatobiliary disorders                              | Hepatitis cholestatic                                       | 4          | 0              | 3         |
|                |  | Jaundice  | 8          | 0              | 6         |
|                |  | Hepatic function abnormal                                   | 14         | 0              | 5         |
|                |  | Hepatitis   | 11         | 0              | 6         |
|                |  | <b>Hepatobiliary disorders</b>                              | <b>37</b>  | <b>0</b>       | <b>20</b> |
|                | Infections and infestations                          | Candidiasis   | 2          | 0              | 0         |

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| 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         |
|                |   | <b>Infections and infestations</b>   | <b>10</b>      | <b>1 3</b>  |
|                | Injury, poisoning and procedural complications                      | Medication error   | 1              | 0 1         |
|                |   | Accidental overdose  | 1              | 0 1         |
|                |   | <b>Injury, poisoning and procedural complications</b>                      | <b>2</b>       | <b>0 2</b>  |
|                | 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         |
|                |   | <b>Investigations</b>  | <b>12</b>      | <b>0 7</b>  |
|                | 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         |
|                |   | <b>Metabolism and nutrition disorders</b>                                  | <b>25</b>      | <b>1 12</b> |
|                | 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         |
|                |   | <b>Musculoskeletal and connective tissue disorders</b>                     | <b>16</b>      | <b>0 9</b>  |
|                | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | Leukaemia granulocytic   | 1              | 0 0         |
|                |   | <b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b> | <b>1</b>       | <b>0 0</b>  |
|                | Nervous system disorders  | Facial palsy   | 1              | 0 1         |
|                |   | Parosmia   | 1              | 0 1         |

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| 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         |
|                       |                          | Hyperesthesia                   | 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         |
|                       |                          | <b>Nervous system disorders</b> | <b>121</b>     | <b>1 53</b> |
| Psychiatric disorders | 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         |

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| 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         |
|                |   | <b>Psychiatric disorders</b>                    | <b>114</b> | <b>1</b>       | <b>64</b> |
| Reaction Count | 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         |
|                |   | <b>Renal and urinary disorders</b>              | <b>23</b>  | <b>3</b>       | <b>13</b> |
|                |   |   |            |                |           |
| Reaction Count | 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         |
|                |   | <b>Reproductive system and breast disorders</b> | <b>18</b>  | <b>0</b>       | <b>14</b> |
|                |   |   |            |                |           |
| Reaction Count | Respiratory, thoracic and mediastinal disorders | Dyspnoea  | 3          | 0              | 0         |
|                |   | Respiratory distress                            | 1          | 0              | 0         |

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|                | 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          |
|                |   | <b>Respiratory, thoracic and mediastinal disorders</b> | <b>12</b>  | <b>1</b>       | <b>3</b>   |
|                | 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          |
|                |   | <b>Skin and subcutaneous tissue disorders</b>          | <b>144</b> | <b>0</b>       | <b>96</b>  |
|                | Surgical and medical procedures                 | Therapy regimen changed                                | 2          | 0              | 0          |
|                |   | <b>Surgical and medical procedures</b>                 | <b>2</b>   | <b>0</b>       | <b>0</b>   |
|                | 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          |
|                |   | <b>Vascular disorders</b>                              | <b>46</b>  | <b>2</b>       | <b>22</b>  |
|                | <b>Reaction</b>                                 |  | <b>813</b> | <b>18</b>      | <b>447</b> |