

# THERAPEUTIC GOODS ADMINISTRATION MEDICINE SUMMARY

TRIFLUOPERAZINE HYDROCHLORIDE

Layer 1 of 1

|  |                               | ALL REPORT DATES           |       |                              |
|--|-------------------------------|----------------------------|-------|------------------------------|
|  |                               | Causality Unclear Excluded |       |                              |
|  |                               | Total                      | Death | Sole<br>Outcome<br>Suspected |
| - Cases Including Medicine                 |                               | 274                        | 5     | 129                          |
| - Occurrences of Medicine                  |                               | 284                        | 5     | 129                          |
| - Reactions Related to Medicine            |                               | 585                        | 14    | 263                          |
| Blood and lymphatic system disorders       | Agranulocytosis               | 4                          | 1     | 0                            |
|  | Anaemia                       | 4                          | 0     | 1                            |
|  | Anaemia macrocytic            | 1                          | 0     | 0                            |
|  | Leukocytosis                  | 5                          | 0     | 0                            |
|  | Leukopenia                    | 1                          | 0     | 0                            |
|  | Neutropenia                   | 4                          | 0     | 0                            |
|  | Splenomegaly                  | 2                          | 0     | 1                            |
|  | Thrombocythaemia              | 1                          | 0     | 0                            |
|  | Thrombocytopenia              | 4                          | 0     | 3                            |
| Cardiac disorders                          | Cardiac disorder              | 1                          | 1     | 0                            |
|  | Palpitations                  | 1                          | 0     | 0                            |
|  | Tachycardia                   | 6                          | 0     | 2                            |
| Congenital, familial and genetic disorders | Congenital hand malformation  | 1                          | 0     | 1                            |
|  | Gastrointestinal malformation | 1                          | 0     | 0                            |
|  | Ventricular septal defect     | 1                          | 0     | 1                            |
| Ear and labyrinth disorders                | Ear pain                      | 1                          | 0     | 1                            |
|  | Hyperacusis                   | 2                          | 0     | 2                            |
|  | Tinnitus                      | 2                          | 0     | 2                            |
|  | Vertigo                       | 1                          | 0     | 1                            |
| Endocrine disorders                        | Diabetes insipidus            | 1                          | 0     | 0                            |
| Eye disorders                              | Accommodation disorder        | 1                          | 0     | 1                            |
|  | Conjunctivitis                | 1                          | 0     | 0                            |
|  | Diplopia                      | 1                          | 0     | 1                            |
|  | Mydriasis                     | 1                          | 0     | 1                            |
|  | Oculogyration                 | 8                          | 0     | 8                            |
|  | Photophobia                   | 1                          | 0     | 0                            |
|  | Visual disturbance            | 7                          | 0     | 4                            |
| Gastrointestinal disorders                 | Abdominal pain                | 5                          | 0     | 4                            |

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| Gastrointestinal disorders                           | Ascites                   | 1            | 1 | 0 |
|  | Constipation              | 6            | 0 | 2 |
|  | Diarrhoea                 | 1            | 0 | 0 |
|  | Dry mouth                 | 3            | 0 | 1 |
|  | Dysphagia                 | 3            | 0 | 3 |
|  | Glossitis                 | 1            | 0 | 0 |
|  | Haematemesis              | 1            | 1 | 0 |
|  | Mouth ulceration          | 3            | 0 | 1 |
|  | Nausea                    | 6            | 0 | 5 |
|  | Oesophagitis ulcerative   | 1            | 0 | 1 |
|  | Salivary hypersecretion   | 2            | 0 | 1 |
|  | Tongue oedema             | 1            | 0 | 1 |
|  | Tooth discolouration      | 1            | 0 | 1 |
|  | Vomiting                  | 5            | 0 | 4 |
| General disorders and administration site conditions | Asthenia                  | 2            | 0 | 1 |
|  | Chest pain                | 1            | 0 | 0 |
|  | Chills                    | 3            | 0 | 0 |
|  | Drug ineffective          | 3            | 0 | 1 |
|  | Drug withdrawal syndrome  | 3            | 0 | 2 |
|  | Face oedema               | 3            | 0 | 1 |
|  | Fatigue                   | 3            | 0 | 1 |
|  | Gait disturbance          | 4            | 0 | 3 |
|  | Granuloma                 | 1            | 0 | 1 |
|  | Gravitational oedema      | 1            | 0 | 0 |
|  | Hyperthermia malignant    | 1            | 0 | 0 |
|  | Hypothermia               | 2            | 0 | 2 |
|  | Oedema                    | 2            | 0 | 1 |
|  | Oedema peripheral         | 2            | 0 | 0 |
|  | Pain                      | 3            | 0 | 3 |
|  | Pyrexia                   | 9            | 0 | 1 |
|  | Sudden death              | 1            | 1 | 0 |
| Hepatobiliary disorders                              | Hepatic cirrhosis         | 1            | 1 | 0 |
|  | Hepatic failure           | 1            | 1 | 0 |
|  | Hepatic function abnormal | 4            | 0 | 2 |
|  | Hepatic steatosis         | 1            | 0 | 0 |

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| Hepatobiliary disorders                         | Hepatitis                                   | 3 | 0 | 1            |
|   | Hepatitis cholestatic                       | 3 | 0 | 1            |
|   | Hepatocellular damage                       | 1 | 0 | 0            |
|   | Hepatomegaly                                | 4 | 0 | 0            |
|   | Hyperbilirubinaemia                         | 1 | 0 | 1            |
|   | Jaundice                                    | 8 | 1 | 1            |
| Infections and infestations                     | Rhinitis                                    | 1 | 0 | 1            |
|   | Sepsis                                      | 2 | 1 | 0            |
|   | Sinusitis                                   | 1 | 0 | 1            |
| Injury, poisoning and procedural complications  | Fall  | 1 | 0 | 0            |
|   | Overdose                                    | 2 | 0 | 0            |
| Investigations                                  | Blood alkaline phosphatase increased        | 2 | 0 | 1            |
|   | Blood creatine phosphokinase increased      | 8 | 0 | 2            |
|   | Body temperature increased                  | 1 | 0 | 1            |
|   | Red blood cell sedimentation rate increased | 2 | 0 | 1            |
|   | Transaminases increased                     | 1 | 0 | 0            |
|   | Weight decreased                            | 4 | 0 | 1            |
|   | Weight increased                            | 3 | 0 | 2            |
| Metabolism and nutrition disorders              | Anorexia                                    | 3 | 1 | 2            |
|   | Dehydration                                 | 3 | 0 | 1            |
|   | Hypercholesterolaemia                       | 1 | 0 | 0            |
|   | Hyperglycaemia                              | 1 | 0 | 0            |
|   | Hypertriglyceridaemia                       | 1 | 0 | 0            |
|   | Hypocalcaemia                               | 1 | 0 | 0            |
|   | Hypokalaemia                                | 3 | 0 | 0            |
|   | Hyponatraemia                               | 7 | 0 | 2            |
|   | Polydipsia                                  | 1 | 0 | 1            |
|   | Tetany                                      | 1 | 0 | 1            |
| Musculoskeletal and connective tissue disorders | Arthralgia                                  | 3 | 0 | 1            |
|   | Muscle rigidity                             | 1 | 0 | 0            |
|   | Myalgia                                     | 4 | 0 | 3            |
|   | Osteoporosis                                | 1 | 0 | 0            |
|   | Pathological fracture                       | 1 | 0 | 0            |
|   | Torticollis                                 | 2 | 0 | 2            |
| Neoplasms benign, malignant and unspecif        | Breast cancer female                        | 1 | 0 | 0            |

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| Nervous system disorders      | Amnesia                        | 2  | 0 | 1            |
|                               | Cerebral haemorrhage           | 2  | 2 | 0            |
|                               | Choreoathetosis                | 3  | 0 | 2            |
|                               | Consciousness fluctuating      | 2  | 0 | 0            |
|                               | Convulsion                     | 6  | 0 | 2            |
|                               | Coordination abnormal          | 5  | 0 | 2            |
|                               | Disturbance in attention       | 1  | 0 | 0            |
|                               | Dizziness                      | 3  | 0 | 2            |
|                               | Dysarthria                     | 1  | 0 | 0            |
|                               | Dyskinesia                     | 14 | 0 | 6            |
|                               | Dystonia                       | 22 | 0 | 15           |
|                               | Encephalopathy                 | 2  | 1 | 0            |
|                               | Extrapyramidal disorder        | 32 | 0 | 21           |
|                               | Headache                       | 8  | 0 | 5            |
|                               | Hyperaesthesia                 | 1  | 0 | 0            |
|                               | Hyperkinesia                   | 20 | 0 | 14           |
|                               | Hyperreflexia                  | 1  | 0 | 1            |
|                               | Hypertonia                     | 11 | 0 | 6            |
|                               | Hypoesthesia                   | 1  | 0 | 1            |
|                               | Loss of consciousness          | 1  | 0 | 0            |
|                               | Meningism                      | 1  | 0 | 0            |
|                               | Migraine                       | 1  | 0 | 0            |
|                               | Movement disorder              | 1  | 0 | 1            |
|                               | Myoclonus                      | 1  | 0 | 0            |
|                               | Neuroleptic malignant syndrome | 11 | 1 | 3            |
|                               | Neuropathy peripheral          | 1  | 0 | 0            |
|                               | Opisthotonus                   | 1  | 0 | 1            |
|                               | Paraesthesia                   | 5  | 0 | 3            |
|                               | Paralysis                      | 1  | 0 | 1            |
|                               | Paresis                        | 1  | 0 | 1            |
|                               | Somnolence                     | 7  | 0 | 2            |
|                               | Speech disorder                | 4  | 0 | 3            |
|                               | Stupor                         | 1  | 0 | 1            |
|                               | Syncope                        | 2  | 0 | 2            |
|                               | Tardive dyskinesia             | 21 | 0 | 8            |

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| Nervous system disorders                        | Tremor                | 13 | 0 | 7            |
| Pregnancy, puerperium and perinatal conditi     | Intra-uterine death   | 1  | 0 | 0            |
| Psychiatric disorders                           | Agitation             | 7  | 0 | 5            |
|   | Anxiety               | 1  | 0 | 0            |
|   | Apathy                | 1  | 0 | 1            |
|   | Bruxism               | 1  | 0 | 0            |
|   | Catatonia             | 2  | 0 | 0            |
|   | Confusional state     | 6  | 0 | 0            |
|   | Delirium              | 1  | 0 | 0            |
|   | Depersonalisation     | 2  | 0 | 2            |
|   | Depression            | 2  | 0 | 2            |
|   | Euphoric mood         | 1  | 0 | 0            |
|   | Hallucination         | 7  | 0 | 2            |
|   | Hallucination, visual | 1  | 0 | 0            |
|   | Insomnia              | 5  | 0 | 4            |
|   | Libido decreased      | 1  | 0 | 1            |
|   | Mood swings           | 1  | 0 | 0            |
|   | Nervousness           | 1  | 0 | 1            |
|   | Nightmare             | 1  | 0 | 1            |
|   | Psychotic disorder    | 2  | 0 | 1            |
|   | Suicide attempt       | 1  | 0 | 0            |
|   | Thinking abnormal     | 3  | 0 | 2            |
| Renal and urinary disorders                     | Anuria                | 1  | 0 | 0            |
|   | Haematuria            | 1  | 0 | 0            |
|   | Micturition disorder  | 2  | 0 | 0            |
|   | Pollakiuria           | 1  | 0 | 1            |
|   | Renal failure acute   | 1  | 0 | 0            |
|   | Renal impairment      | 3  | 0 | 0            |
|   | Urinary retention     | 1  | 0 | 1            |
| Reproductive system and breast disorders        | Amenorrhoea           | 2  | 0 | 1            |
|   | Breast enlargement    | 1  | 0 | 0            |
|   | Galactorrhoea         | 2  | 0 | 0            |
|   | Sexual dysfunction    | 1  | 0 | 1            |
| Respiratory, thoracic and mediastinal disorders | Cough                 | 1  | 0 | 0            |
|   | Dyspnoea              | 6  | 0 | 3            |

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| Respiratory, thoracic and mediastinal disorders | Epistaxis                  | 1 | 0 | 0            |
|   | Productive cough           | 1 | 0 | 0            |
| Skin and subcutaneous tissue disorders          | Acne                       | 1 | 0 | 1            |
|   | Alopecia                   | 1 | 0 | 0            |
|   | Angioedema                 | 3 | 0 | 1            |
|   | Dermatitis                 | 1 | 0 | 1            |
|   | Dermatitis bullous         | 2 | 0 | 0            |
|   | Dermatitis exfoliative     | 1 | 0 | 1            |
|   | Hyperhidrosis              | 6 | 0 | 3            |
|   | Photosensitivity reaction  | 4 | 0 | 2            |
|   | Pruritus                   | 4 | 0 | 1            |
|   | Rash                       | 8 | 0 | 2            |
|   | Rash erythematous          | 2 | 0 | 1            |
|   | Rash maculo-papular        | 7 | 0 | 5            |
|   | Skin discolouration        | 2 | 0 | 1            |
|   | Toxic epidermal necrolysis | 1 | 0 | 0            |
|   | Urticaria                  | 4 | 0 | 1            |
| Surgical and medical procedures                 | Therapy regimen changed    | 1 | 0 | 0            |
| Vascular disorders                              | Flushing                   | 1 | 0 | 0            |
|   | Haemorrhage                | 2 | 0 | 0            |
|   | Hypertension               | 6 | 0 | 1            |
|   | Hypotension                | 2 | 0 | 0            |
|   | Orthostatic hypotension    | 2 | 0 | 1            |
|   | Pallor                     | 1 | 0 | 0            |
|   | Thrombosis                 | 1 | 0 | 0            |
|   | Vein disorder              | 1 | 0 | 1            |