

## Case Series Drug Analysis Print

Name: FOI 24/327 - Pethidine

Report Run Date: 23-Apr-2024  
Data Lock Date: 22-Apr-2024 18:30:03  
Earliest Reaction Date: 01-Mar-1961  
MedDRA Version: MedDRA 26.1  
FOI 24/327 - CEC 182217  
Pethidine:

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Earliest Reaction Date: 01-Mar-1961

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| Reaction Name                                     | Total     | Fatal    |
|---|-----------|----------|
| <b>Cardiac disorders</b>                          |           |          |
| <i>Cardiac signs and symptoms NEC</i>             |           |          |
| Palpitations                                      | 2         | 0        |
| <i>Ischaemic coronary artery disorders</i>        |           |          |
| Myocardial infarction                             | 2         | 2        |
| <i>Rate and rhythm disorders NEC</i>              |           |          |
| Arrhythmia  | 1         | 0        |
| Bradycardia                                       | 4         | 0        |
| Tachycardia                                       | 10        | 0        |
| <i>Ventricular arrhythmias and cardiac arrest</i> |           |          |
| Cardiac arrest                                    | 5         | 2        |
| Cardio-respiratory arrest                         | 1         | 1        |
| <b>Cardiac disorders SOC TOTAL</b>                | <b>25</b> | <b>5</b> |

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| Reaction Name  | Total    | Fatal    |
|--|----------|----------|
| <b>Congenital disorders</b>  |          |          |
| <i>Cardiac disorders congenital NEC</i>                                    |          |          |
| Heart disease congenital   | 1        | 0        |
| <i>Congenital disorders NEC</i>  |          |          |
| Multiple congenital abnormalities  | 1        | 0        |
| <i>Male reproductive tract disorders congenital</i>                        |          |          |
| Hypospadias  | 1        | 0        |
| <i>Musculoskeletal and connective tissue disorders of limbs congenital</i> |          |          |
| Congenital musculoskeletal disorder of limbs                               | 1        | 0        |
| <i>Musculoskeletal disorders congenital NEC</i>                            |          |          |
| Congenital musculoskeletal disorder  | 1        | 0        |
| Dysmorphism  | 1        | 0        |
| <i>Renal and urinary tract disorders congenital NEC</i>                    |          |          |
| Urinary tract malformation   | 1        | 0        |
| <i>Renal disorders congenital</i>  |          |          |
| Congenital cystic kidney disease   | 1        | 1        |
| <b>Congenital disorders SOC TOTAL</b>                                      | <b>8</b> | <b>1</b> |

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| Reaction Name                         | Total    | Fatal    |
|---------------------------------------|----------|----------|
| <b>Endocrine disorders</b>            |          |          |
| <i>Adrenal cortical hypofunctions</i> |          |          |
| Addison's disease                     | 1        | 0        |
| <b>Endocrine disorders SOC TOTAL</b>  | <b>1</b> | <b>0</b> |

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| Reaction Name   | Total    | Fatal    |
|---|----------|----------|
| <b>Eye disorders</b>  |          |          |
| <i>Iris and uveal tract infections, irritations and inflammations</i>   |          |          |
| Iridocyclitis   | 1        | 0        |
| <i>Lacrimation disorders</i>  |          |          |
| Lacrimation increased   | 1        | 0        |
| <i>Lid, lash and lacrimal infections, irritations and inflammations</i> |          |          |
| Swelling of eyelid  | 1        | 0        |
| <i>Ocular disorders NEC</i>   |          |          |
| Eye pain  | 1        | 0        |
| <i>Ocular infections, inflammations and associated manifestations</i>   |          |          |
| Ocular hyperaemia   | 1        | 0        |
| <i>Ocular nerve and muscle disorders</i>                                |          |          |
| Oculogyric crisis   | 1        | 0        |
| <i>Ocular sensation disorders</i>                                       |          |          |
| Photophobia   | 1        | 0        |
| <i>Visual impairment and blindness (excl colour blindness)</i>          |          |          |
| Visual impairment   | 1        | 0        |
| <b>Eye disorders SOC TOTAL</b>  | <b>8</b> | <b>0</b> |

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| Reaction Name  | Total     | Fatal    |
|--|-----------|----------|
| <b>Gastrointestinal disorders</b>                                  |           |          |
| <i>Anal and rectal pains</i>                                       |           |          |
| Proctalgia   | 1         | 0        |
| <i>Dental surface disorders</i>                                    |           |          |
| Enamel anomaly   | 1         | 0        |
| Tooth discolouration   | 1         | 0        |
| <i>Diarrhoea (excl infective)</i>                                  |           |          |
| Diarrhoea  | 1         | 0        |
| <i>Gastrointestinal and abdominal pains (excl oral and throat)</i> |           |          |
| Abdominal pain lower   | 1         | 0        |
| <i>Gastrointestinal atonic and hypomotility disorders NEC</i>      |           |          |
| Constipation   | 2         | 0        |
| <i>Gastrointestinal signs and symptoms NEC</i>                     |           |          |
| Dysphagia  | 1         | 0        |
| <i>Nausea and vomiting symptoms</i>                                |           |          |
| Nausea   | 15        | 0        |
| Vomiting   | 29        | 0        |
| <i>Oral soft tissue swelling and oedema</i>                        |           |          |
| Lip swelling   | 1         | 0        |
| <i>Tongue signs and symptoms</i>                                   |           |          |
| Swollen tongue   | 5         | 0        |
| <b>Gastrointestinal disorders SOC TOTAL</b>                        | <b>58</b> | <b>0</b> |

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| Reaction Name                                      | Total | Fatal |
|--|-------|-------|
| <b>General disorders</b>                           |       |       |
| <i>Application and instillation site reactions</i> |       |       |
| Application site pruritus                          | 1     | 0     |
| Application site vesicles                          | 2     | 0     |
| <i>Asthenic conditions</i>                         |       |       |
| Asthenia   | 3     | 0     |
| Fatigue  | 1     | 0     |
| Malaise  | 7     | 0     |
| <i>Body temperature altered</i>                    |       |       |
| Hypothermia  | 1     | 0     |
| <i>Death and sudden death</i>                      |       |       |
| Sudden death                                       | 1     | 1     |
| <i>Febrile disorders</i>                           |       |       |
| Pyrexia  | 4     | 0     |
| <i>Feelings and sensations NEC</i>                 |       |       |
| Feeling hot  | 4     | 0     |
| <i>General signs and symptoms NEC</i>              |       |       |
| Crying   | 1     | 0     |
| General physical health deterioration              | 1     | 0     |
| Illness  | 2     | 0     |
| Local reaction                                     | 1     | 0     |
| Peripheral swelling                                | 2     | 0     |
| Secretion discharge                                | 1     | 0     |
| Swelling   | 3     | 0     |
| Swelling face                                      | 1     | 0     |
| <i>Implant and catheter site reactions</i>         |       |       |
| Catheter site pain                                 | 1     | 0     |
| Catheter site related reaction                     | 2     | 0     |
| <i>Infusion site reactions</i>                     |       |       |
| Infusion site phlebitis                            | 1     | 0     |
| <i>Injection site reactions</i>                    |       |       |
| Injection site erythema                            | 3     | 0     |
| Injection site haematoma                           | 1     | 0     |
| Injection site haemorrhage                         | 1     | 0     |
| Injection site inflammation                        | 1     | 0     |
| Injection site irritation                          | 1     | 0     |
| Injection site pain                                | 9     | 0     |
| Injection site rash                                | 3     | 0     |
| Injection site reaction                            | 11    | 0     |
| Injection site swelling                            | 1     | 0     |
| Injection site urticaria                           | 7     | 0     |
| Injection site vesicles                            | 1     | 0     |
| <i>Interactions</i>                                |       |       |
| Drug interaction                                   | 4     | 0     |
| Inhibitory drug interaction                        | 1     | 0     |
| Potentiating drug interaction                      | 1     | 0     |
| <i>Oedema NEC</i>                                  |       |       |
| Face oedema  | 2     | 0     |
| Oedema   | 3     | 0     |
| <i>Pain and discomfort NEC</i>                     |       |       |
| Chest pain   | 2     | 0     |
| Discomfort   | 1     | 0     |
| Pain   | 4     | 0     |
| <i>Therapeutic and nontherapeutic responses</i>    |       |       |

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| Reaction Name                                     | Total      | Fatal    |
|---|------------|----------|
| <b>General disorders</b> General disorders cont'd |            |          |
| Adverse drug reaction                             | 1          | 0        |
| Drug ineffective                                  | 5          | 0        |
| Drug intolerance                                  | 2          | 0        |
| Therapeutic product effect incomplete             | 1          | 0        |
| Therapeutic response increased                    | 1          | 0        |
| Treatment failure                                 | 1          | 0        |
| <b>Withdrawal and rebound effects</b>             |            |          |
| Drug withdrawal syndrome                          | 2          | 0        |
| Drug withdrawal syndrome neonatal                 | 1          | 0        |
| Withdrawal syndrome                               | 1          | 0        |
| <b>General disorders SOC TOTAL</b>                | <b>112</b> | <b>1</b> |



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| Reaction Name                      | Total    | Fatal    |
|------------------------------------|----------|----------|
| <b>Hepatic disorders</b>           |          |          |
| <i>Cholestasis and jaundice</i>    |          |          |
| Jaundice                           | 4        | 1        |
| Jaundice cholestatic               | 1        | 0        |
| <b>Hepatic disorders SOC TOTAL</b> | <b>5</b> | <b>1</b> |

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| <b>Reaction Name</b>   | <b>Total</b> | <b>Fatal</b> |
|--|--------------|--------------|
| <b>Immune system disorders</b>                                       |              |              |
| <i>Allergic conditions NEC</i>                                       |              |              |
| Hypersensitivity   | 2            | 0            |
| <i>Allergies to foods, food additives, drugs and other chemicals</i> |              |              |
| Drug hypersensitivity  | 5            | 0            |
| <i>Anaphylactic and anaphylactoid responses</i>                      |              |              |
| Anaphylactic reaction  | 8            | 1            |
| Anaphylactic shock   | 1            | 1            |
| <b>Immune system disorders SOC TOTAL</b>                             | <b>16</b>    | <b>2</b>     |

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| Reaction Name   | Total     | Fatal    |
|---|-----------|----------|
| <b>Infections</b>   |           |          |
| <i><b>Borrelial infections</b></i>                            |           |          |
| Lyme disease  | 1         | 0        |
| <i><b>Eye and eyelid infections</b></i>                       |           |          |
| Conjunctivitis  | 1         | 0        |
| <i><b>Infections NEC</b></i>                                  |           |          |
| Infection   | 1         | 0        |
| <i><b>Lower respiratory tract and lung infections</b></i>     |           |          |
| Lower respiratory tract infection                             | 1         | 0        |
| Pneumonia   | 2         | 0        |
| <i><b>Sepsis, bacteraemia, viraemia and fungaemia NEC</b></i> |           |          |
| Sepsis  | 1         | 0        |
| <i><b>Staphylococcal infections</b></i>                       |           |          |
| Staphylococcal infection                                      | 1         | 0        |
| <i><b>Upper respiratory tract infections</b></i>              |           |          |
| Nasopharyngitis   | 1         | 0        |
| <i><b>Viral infections NEC</b></i>                            |           |          |
| Viral infection   | 1         | 0        |
| <b>Infections SOC TOTAL</b>                                   | <b>10</b> | <b>0</b> |

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| Reaction Name   | Total     | Fatal    |
|---|-----------|----------|
| <b>Injuries</b>   |           |          |
| <i><b>Anaesthetic and allied procedural complications</b></i>             |           |          |
| Anaesthetic complication  | 1         | 0        |
| <i><b>Exposures associated with pregnancy, delivery and lactation</b></i> |           |          |
| Exposure during pregnancy   | 5         | 0        |
| Foetal exposure during pregnancy  | 5         | 0        |
| Maternal exposure during delivery   | 1         | 0        |
| Maternal exposure during pregnancy  | 2         | 0        |
| <i><b>Intentional product use issues</b></i>                              |           |          |
| Intentional product use issue   | 1         | 0        |
| <i><b>Medication errors, product use errors and issues NEC</b></i>        |           |          |
| Product use in unapproved indication                                      | 2         | 0        |
| <i><b>Non-site specific injuries NEC</b></i>                              |           |          |
| Fall  | 1         | 0        |
| <i><b>Non-site specific procedural complications</b></i>                  |           |          |
| Post procedural hypotension   | 1         | 0        |
| <i><b>Off label uses</b></i>  |           |          |
| Off label use   | 2         | 0        |
| <i><b>Overdoses NEC</b></i>   |           |          |
| Intentional overdose  | 2         | 0        |
| Overdose  | 2         | 0        |
| <i><b>Poisoning and toxicity</b></i>                                      |           |          |
| Metal poisoning   | 1         | 0        |
| Toxicity to various agents  | 1         | 0        |
| <i><b>Product administration errors and issues</b></i>                    |           |          |
| Contraindicated product administered                                      | 1         | 0        |
| Incorrect dose administered   | 1         | 0        |
| Incorrect route of product administration                                 | 1         | 0        |
| Product administration error  | 2         | 0        |
| <i><b>Product monitoring errors and issues</b></i>                        |           |          |
| Documented hypersensitivity to administered product                       | 1         | 0        |
| <i><b>Reproductive system and breast injuries</b></i>                     |           |          |
| Uterine rupture   | 1         | 0        |
| <b>Injuries SOC TOTAL</b>   | <b>34</b> | <b>0</b> |

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| Reaction Name   | Total     | Fatal    |
|---|-----------|----------|
| <b>Investigations</b>   |           |          |
| <i><b>Blood gas and acid base analyses</b></i>                        |           |          |
| Oxygen saturation decreased   | 2         | 0        |
| <i><b>Coagulation and bleeding analyses</b></i>                       |           |          |
| International normalised ratio fluctuation                            | 1         | 0        |
| <i><b>ECG investigations</b></i>                                      |           |          |
| Electrocardiogram QT prolonged  | 1         | 0        |
| Electrocardiogram abnormal  | 1         | 0        |
| <i><b>Haematological analyses NEC</b></i>                             |           |          |
| Red blood cell sedimentation rate increased                           | 1         | 0        |
| <i><b>Heart rate and pulse investigations</b></i>                     |           |          |
| Heart rate increased  | 1         | 0        |
| <i><b>Hepatobiliary function diagnostic procedures</b></i>            |           |          |
| Alanine aminotransferase increased                                    | 1         | 0        |
| Liver function test abnormal  | 1         | 0        |
| Liver function test increased   | 1         | 0        |
| <i><b>Neurologic diagnostic procedures</b></i>                        |           |          |
| Coma scale abnormal   | 1         | 0        |
| <i><b>Physical examination procedures and organ system status</b></i> |           |          |
| Body temperature increased  | 2         | 0        |
| Respiratory rate decreased  | 1         | 0        |
| <i><b>Platelet analyses</b></i>                                       |           |          |
| Platelet count increased  | 1         | 0        |
| <i><b>Protein analyses NEC</b></i>                                    |           |          |
| C-reactive protein increased  | 1         | 0        |
| <i><b>Red blood cell analyses</b></i>                                 |           |          |
| Haemoglobin decreased   | 1         | 0        |
| <i><b>Vascular tests NEC (incl blood pressure)</b></i>                |           |          |
| Blood pressure increased  | 2         | 0        |
| Blood pressure systolic increased                                     | 1         | 0        |
| <i><b>White blood cell analyses</b></i>                               |           |          |
| Eosinophil count increased  | 1         | 0        |
| <b>Investigations SOC TOTAL</b>                                       | <b>21</b> | <b>0</b> |

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| Reaction Name                            | Total    | Fatal    |
|--|----------|----------|
| <b>Metabolic disorders</b>               |          |          |
| <i>Calcium metabolism disorders</i>      |          |          |
| Tetany                                   | 2        | 0        |
| <i>General nutritional disorders NEC</i> |          |          |
| Feeding disorder                         | 1        | 0        |
| <i>Iron deficiencies</i>                 |          |          |
| Iron deficiency                          | 1        | 0        |
| <i>Potassium imbalance</i>               |          |          |
| Hyperkalaemia                            | 1        | 0        |
| <b>Metabolic disorders SOC TOTAL</b>     | <b>5</b> | <b>0</b> |

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| Reaction Name  | Total     | Fatal    |
|--|-----------|----------|
| <b>Muscle &amp; tissue disorders</b>                             |           |          |
| <i>Joint related signs and symptoms</i>                          |           |          |
| Joint noise  | 1         | 0        |
| <i>Muscle infections and inflammations</i>                       |           |          |
| Myositis   | 1         | 0        |
| <i>Muscle pains</i>  |           |          |
| Fibromyalgia   | 1         | 0        |
| Myalgia  | 1         | 0        |
| <i>Muscle related signs and symptoms NEC</i>                     |           |          |
| Muscle spasms  | 1         | 0        |
| Muscle twitching   | 1         | 0        |
| <i>Musculoskeletal and connective tissue conditions NEC</i>      |           |          |
| Muscle contracture   | 1         | 0        |
| Posture abnormal   | 1         | 0        |
| <i>Musculoskeletal and connective tissue pain and discomfort</i> |           |          |
| Back pain  | 1         | 0        |
| Limb discomfort  | 1         | 0        |
| Pain in extremity  | 1         | 0        |
| <i>Myopathies</i>  |           |          |
| Myopathy   | 1         | 0        |
| <b>Muscle &amp; tissue disorders SOC TOTAL</b>                   | <b>12</b> | <b>0</b> |

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|--|-------|-------|
| <b>Nervous system disorders</b>                          |       |       |
| <i>Coma states</i>                                       |       |       |
| Coma   | 2     | 0     |
| <i>Coordination and balance disturbances</i>             |       |       |
| Balance disorder   | 1     | 0     |
| Coordination abnormal                                    | 2     | 0     |
| Nystagmus  | 1     | 0     |
| <i>Disturbances in consciousness NEC</i>                 |       |       |
| Depressed level of consciousness                         | 2     | 0     |
| Lethargy   | 1     | 0     |
| Loss of consciousness                                    | 3     | 0     |
| Somnolence   | 11    | 0     |
| Syncope  | 8     | 0     |
| <i>Dyskinesias and movement disorders NEC</i>            |       |       |
| Dyskinesia   | 1     | 0     |
| Extrapyramidal disorder                                  | 1     | 0     |
| <i>Dystonias</i>   |       |       |
| Dystonia   | 1     | 0     |
| Opisthotonus   | 2     | 0     |
| <i>Facial cranial nerve disorders</i>                    |       |       |
| Bell's palsy   | 1     | 0     |
| <i>Generalised tonic-clonic seizures</i>                 |       |       |
| Generalised tonic-clonic seizure                         | 4     | 0     |
| <i>Headaches NEC</i>                                     |       |       |
| Headache   | 4     | 0     |
| <i>Memory loss (excl dementia)</i>                       |       |       |
| Memory impairment  | 1     | 0     |
| <i>Mental impairment (excl dementia and memory loss)</i> |       |       |
| Cognitive disorder                                       | 1     | 0     |
| Mental impairment  | 2     | 0     |
| <i>Muscle tone abnormal</i>                              |       |       |
| Hypotonia  | 1     | 0     |
| Serotonin syndrome                                       | 1     | 0     |
| <i>Nervous system disorders NEC</i>                      |       |       |
| Psychomotor skills impaired                              | 1     | 0     |
| <i>Neurological signs and symptoms NEC</i>               |       |       |
| Dizziness  | 9     | 0     |
| Grimacing  | 1     | 0     |
| Presyncope   | 1     | 0     |
| Slow response to stimuli                                 | 3     | 0     |
| Unresponsive to stimuli                                  | 3     | 0     |
| <i>Paraesthesias and dysaesthesias</i>                   |       |       |
| Hypoaesthesia  | 3     | 0     |
| Paraesthesia   | 7     | 0     |
| <i>Paralysis and paresis (excl cranial nerve)</i>        |       |       |
| Paralysis  | 1     | 0     |
| <i>Seizures and seizure disorders NEC</i>                |       |       |
| Epilepsy   | 3     | 0     |
| Seizure  | 7     | 0     |
| <i>Sensory abnormalities NEC</i>                         |       |       |
| Complex regional pain syndrome                           | 1     | 0     |
| Dysgeusia  | 1     | 0     |
| <i>Speech and language abnormalities</i>                 |       |       |
| Dysarthria   | 2     | 0     |



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|---|-----------|----------|
| <b>Nervous system disorders</b>           |           |          |
| <i>Nervous system disorders cont'd</i>    |           |          |
| <b><i>Tremor (excl congenital)</i></b>    |           |          |
| Tremor                                    | 4         | 0        |
| <b>Nervous system disorders SOC TOTAL</b> | <b>98</b> | <b>0</b> |

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| <b>Reaction Name</b>                           | <b>Total</b> | <b>Fatal</b> |
|--|--------------|--------------|
| <b>Pregnancy conditions</b>                    |              |              |
| <i>Failed labour</i>                           |              |              |
| False labour                                   | 1            | 0            |
| <i>Foetal complications NEC</i>                |              |              |
| Foetal acidosis                                | 1            | 0            |
| Foetal distress syndrome                       | 1            | 0            |
| <i>Haemorrhagic complications of pregnancy</i> |              |              |
| Premature separation of placenta               | 1            | 0            |
| <i>Labour onset and length abnormalities</i>   |              |              |
| Premature rupture of membranes                 | 1            | 0            |
| <i>Maternal complications of labour NEC</i>    |              |              |
| Uterine hypertonus                             | 1            | 0            |
| <i>Neonatal hepatobiliary disorders</i>        |              |              |
| Jaundice neonatal                              | 2            | 0            |
| <i>Newborn complications NEC</i>               |              |              |
| Neonatal disorder                              | 1            | 0            |
| <i>Normal newborn status</i>                   |              |              |
| Normal newborn                                 | 1            | 0            |
| <i>Normal pregnancy, labour and delivery</i>   |              |              |
| Uterine contractions during pregnancy          | 1            | 0            |
| <i>Stillbirth and foetal death</i>             |              |              |
| Foetal death                                   | 1            | 1            |
| <b>Pregnancy conditions SOC TOTAL</b>          | <b>12</b>    | <b>1</b>     |

# Case Series Drug Analysis Print

## Name: FOI 24/327 - Pethidine

Report Run Date: 23-Apr-2024

Data Lock Date: 22-Apr-2024 18:30:03

Earliest Reaction Date: 01-Mar-1961

MedDRA Version: MedDRA 26.1

| <b>Reaction Name</b>                          | <b>Total</b> | <b>Fatal</b> |
|---|--------------|--------------|
| <i>Product physical issues</i>                |              |              |
| Product physical issue                        | 1            | 0            |
| <i>Product supply and availability issues</i> |              |              |
| Product availability issue                    | 1            | 0            |
| <b>null SOC TOTAL</b>                         | <b>2</b>     | <b>0</b>     |

# Case Series Drug Analysis Print

Name: FOI 24/327 - Pethidine

Report Run Date: 23-Apr-2024  
Earliest Reaction Date: 01-Mar-1961

Data Lock Date: 22-Apr-2024 18:30:03  
MedDRA Version: MedDRA 26.1

| Reaction Name  | Total     | Fatal    |
|--|-----------|----------|
| <b>Psychiatric disorders</b>                                       |           |          |
| <b><i>Abnormal behaviour NEC</i></b>                               |           |          |
| Abnormal behaviour   | 2         | 0        |
| Behaviour disorder   | 1         | 0        |
| <b><i>Anxiety symptoms</i></b>                                     |           |          |
| Anxiety  | 4         | 0        |
| <b><i>Attention deficit and disruptive behaviour disorders</i></b> |           |          |
| Attention deficit hyperactivity disorder                           | 1         | 0        |
| <b><i>Behaviour and socialisation disturbances</i></b>             |           |          |
| Aggression   | 4         | 0        |
| Paranoia   | 1         | 0        |
| <b><i>Confusion and disorientation</i></b>                         |           |          |
| Confusional state  | 2         | 0        |
| <b><i>Depressive disorders</i></b>                                 |           |          |
| Depression   | 2         | 0        |
| <b><i>Emotional and mood disturbances NEC</i></b>                  |           |          |
| Emotional disorder   | 1         | 0        |
| Frustration tolerance decreased                                    | 2         | 0        |
| <b><i>Hallucinations (excl sleep-related)</i></b>                  |           |          |
| Hallucination  | 2         | 0        |
| Hallucination, visual  | 2         | 0        |
| <b><i>Learning disorders</i></b>                                   |           |          |
| Learning disability  | 1         | 0        |
| Learning disorder  | 2         | 0        |
| <b><i>Mental disorders NEC</i></b>                                 |           |          |
| Mental status changes  | 1         | 0        |
| <b><i>Obsessive-compulsive disorders and symptoms</i></b>          |           |          |
| Obsessive-compulsive disorder                                      | 2         | 0        |
| <b><i>Personality disorders NEC</i></b>                            |           |          |
| Personality disorder   | 2         | 0        |
| <b><i>Pervasive developmental disorders NEC</i></b>                |           |          |
| Autism spectrum disorder   | 3         | 0        |
| <b><i>Psychotic disorder NEC</i></b>                               |           |          |
| Acute psychosis  | 1         | 0        |
| Psychotic disorder   | 2         | 0        |
| <b><i>Schizoaffective and schizophreniform disorders</i></b>       |           |          |
| Schizophreniform disorder  | 1         | 0        |
| <b><i>Sleep disorders NEC</i></b>                                  |           |          |
| Sleep disorder   | 1         | 0        |
| <b><i>Stereotypies and automatisms</i></b>                         |           |          |
| Bruxism  | 1         | 0        |
| <b><i>Substance related and addictive disorders</i></b>            |           |          |
| Drug dependence  | 3         | 0        |
| <b><i>Suicidal and self-injurious behaviour</i></b>                |           |          |
| Suicidal behaviour   | 1         | 0        |
| <b><i>Thinking disturbances</i></b>                                |           |          |
| Thinking abnormal  | 1         | 0        |
| <b>Psychiatric disorders SOC TOTAL</b>                             | <b>46</b> | <b>0</b> |

# Case Series Drug Analysis Print

## Name: FOI 24/327 - Pethidine

Report Run Date: 23-Apr-2024  
 Earliest Reaction Date: 01-Mar-1961

Data Lock Date: 22-Apr-2024 18:30:03  
 MedDRA Version: MedDRA 26.1

| Reaction Name                                    | Total    | Fatal    |
|--|----------|----------|
| <b>Renal &amp; urinary disorders</b>             |          |          |
| <i>Bladder and urethral symptoms</i>             |          |          |
| Pollakiuria                                      | 1        | 0        |
| Urinary retention                                | 1        | 0        |
| <i>Glomerulonephritis and nephrotic syndrome</i> |          |          |
| Glomerulonephritis                               | 1        | 1        |
| <i>Renal failure and impairment</i>              |          |          |
| Acute kidney injury                              | 1        | 0        |
| <i>Renal structural abnormalities and trauma</i> |          |          |
| Pyelocaliectasis                                 | 1        | 0        |
| <i>Urinary abnormalities</i>                     |          |          |
| Chromaturia                                      | 1        | 0        |
| Haematuria                                       | 1        | 0        |
| <i>Urinary tract signs and symptoms NEC</i>      |          |          |
| Renal colic                                      | 1        | 0        |
| <b>Renal &amp; urinary disorders SOC TOTAL</b>   | <b>8</b> | <b>1</b> |

# Case Series Drug Analysis Print

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Data Lock Date: 22-Apr-2024 18:30:03

Earliest Reaction Date: 01-Mar-1961

MedDRA Version: MedDRA 26.1

| Reaction Name  | Total    | Fatal    |
|--|----------|----------|
| <b>Reproductive &amp; breast disorders</b>           |          |          |
| <i>Testicular and epididymal disorders NEC</i>       |          |          |
| Testicular disorder                                  | 1        | 0        |
| <i>Vulvovaginal disorders NEC</i>                    |          |          |
| Vaginal haemorrhage                                  | 1        | 0        |
| <b>Reproductive &amp; breast disorders SOC TOTAL</b> | <b>2</b> | <b>0</b> |

# Case Series Drug Analysis Print

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Report Run Date: 23-Apr-2024  
Earliest Reaction Date: 01-Mar-1961

Data Lock Date: 22-Apr-2024 18:30:03  
MedDRA Version: MedDRA 26.1

| Reaction Name   | Total     | Fatal    |
|---|-----------|----------|
| <b>Respiratory disorders</b>  |           |          |
| <i><b>Breathing abnormalities</b></i>                                   |           |          |
| Dyspnoea  | 9         | 0        |
| Hyperventilation  | 1         | 0        |
| Hypopnoea   | 1         | 0        |
| Respiratory arrest  | 2         | 1        |
| Respiratory depression  | 8         | 1        |
| <i><b>Bronchospasm and obstruction</b></i>                              |           |          |
| Asthma  | 1         | 0        |
| Bronchospasm  | 2         | 0        |
| Obstructive airways disorder  | 1         | 0        |
| Wheezing  | 2         | 0        |
| <i><b>Coughing and associated symptoms</b></i>                          |           |          |
| Cough   | 1         | 0        |
| <i><b>Laryngeal spasm, oedema and obstruction</b></i>                   |           |          |
| Laryngeal oedema  | 1         | 0        |
| Laryngospasm  | 2         | 0        |
| <i><b>Mediastinal disorders</b></i>                                     |           |          |
| Pneumomediastinum   | 1         | 0        |
| <i><b>Neonatal hypoxic conditions</b></i>                               |           |          |
| Infantile apnoea  | 2         | 0        |
| Neonatal respiratory depression   | 2         | 0        |
| Neonatal respiratory distress syndrome                                  | 1         | 0        |
| <i><b>Paranasal sinus disorders (excl infections and neoplasms)</b></i> |           |          |
| Sinus congestion  | 1         | 0        |
| <i><b>Pneumothorax and pleural effusions NEC</b></i>                    |           |          |
| Pneumothorax  | 1         | 0        |
| <i><b>Pulmonary thrombotic and embolic conditions</b></i>               |           |          |
| Obstetrical pulmonary embolism  | 1         | 0        |
| <i><b>Respiratory failures (excl neonatal)</b></i>                      |           |          |
| Acute respiratory failure   | 1         | 0        |
| <i><b>Respiratory tract disorders NEC</b></i>                           |           |          |
| Lung disorder   | 1         | 0        |
| <i><b>Upper respiratory tract signs and symptoms</b></i>                |           |          |
| Rhinorrhoea   | 1         | 0        |
| Throat irritation   | 3         | 0        |
| <b>Respiratory disorders SOC TOTAL</b>                                  | <b>46</b> | <b>2</b> |

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MedDRA Version: MedDRA 26.1

| Reaction Name                                      | Total     | Fatal    |
|--|-----------|----------|
| <b>Skin disorders</b>                              |           |          |
| <b><i>Alopecias</i></b>                            |           |          |
| Alopecia areata                                    | 1         | 0        |
| <b><i>Angioedemas</i></b>                          |           |          |
| Angioedema   | 2         | 0        |
| <b><i>Apocrine and eccrine gland disorders</i></b> |           |          |
| Hyperhidrosis                                      | 8         | 0        |
| <b><i>Bullous conditions</i></b>                   |           |          |
| Blister  | 4         | 0        |
| <b><i>Dermal and epidermal conditions NEC</i></b>  |           |          |
| Pain of skin                                       | 1         | 0        |
| Skin discolouration                                | 3         | 0        |
| Skin reaction                                      | 1         | 0        |
| <b><i>Dermatitis and eczema</i></b>                |           |          |
| Dermatitis allergic                                | 2         | 0        |
| Skin irritation                                    | 1         | 0        |
| <b><i>Erythemas</i></b>                            |           |          |
| Erythema   | 11        | 0        |
| <b><i>Pruritus NEC</i></b>                         |           |          |
| Pruritus   | 4         | 0        |
| <b><i>Psoriatic conditions</i></b>                 |           |          |
| Psoriasis  | 1         | 0        |
| <b><i>Rashes, eruptions and exanthems NEC</i></b>  |           |          |
| Rash   | 15        | 0        |
| Rash erythematous                                  | 3         | 0        |
| Rash macular                                       | 1         | 0        |
| Rash maculo-papular                                | 2         | 0        |
| Rash pruritic                                      | 3         | 0        |
| <b><i>Skin and subcutaneous conditions NEC</i></b> |           |          |
| Subcutaneous emphysema                             | 1         | 0        |
| <b><i>Skin vasculitides</i></b>                    |           |          |
| Vasculitic rash                                    | 1         | 0        |
| <b><i>Urticarias</i></b>                           |           |          |
| Urticaria  | 20        | 0        |
| <b>Skin disorders SOC TOTAL</b>                    | <b>85</b> | <b>0</b> |



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MedDRA Version: MedDRA 26.1

| Reaction Name                         | Total    | Fatal    |
|---------------------------------------|----------|----------|
| <b>Social circumstances</b>           |          |          |
| <i>Educational issues</i>             |          |          |
| Educational problem                   | 1        | 0        |
| <i>Employment issues</i>              |          |          |
| Job dissatisfaction                   | 1        | 0        |
| <b>Social circumstances SOC TOTAL</b> | <b>2</b> | <b>0</b> |

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 MedDRA Version: MedDRA 26.1

| Reaction Name  | Total      | Fatal     |
|--|------------|-----------|
| <b>Vascular disorders</b>  |            |           |
| <i>Circulatory collapse and shock</i>                            |            |           |
| Circulatory collapse   | 3          | 0         |
| <i>Haemorrhages NEC</i>  |            |           |
| Bloody discharge   | 1          | 0         |
| <i>Non-site specific embolism and thrombosis</i>                 |            |           |
| Thrombosis   | 1          | 0         |
| Venous thrombosis  | 1          | 0         |
| <i>Non-site specific necrosis and vascular insufficiency NEC</i> |            |           |
| Ischaemia  | 1          | 0         |
| Vasospasm  | 1          | 0         |
| <i>Non-site specific vascular disorders NEC</i>                  |            |           |
| Vein discolouration  | 2          | 0         |
| <i>Peripheral embolism and thrombosis</i>                        |            |           |
| Thrombophlebitis   | 2          | 0         |
| <i>Peripheral vascular disorders NEC</i>                         |            |           |
| Cyanosis   | 1          | 0         |
| Flushing   | 6          | 0         |
| <i>Phlebitis NEC</i>   |            |           |
| Phlebitis  | 1          | 0         |
| <i>Site specific vascular disorders NEC</i>                      |            |           |
| Pallor   | 5          | 0         |
| <i>Vascular hypertensive disorders NEC</i>                       |            |           |
| Hypertension   | 3          | 0         |
| <i>Vascular hypotensive disorders</i>                            |            |           |
| Hypotension  | 21         | 0         |
| <b>Vascular disorders SOC TOTAL</b>                              | <b>49</b>  | <b>0</b>  |
| <b>TOTAL REACTIONS FOR DRUG</b>                                  | <b>665</b> | <b>14</b> |
| <b>TOTAL REPORTS</b>   | <b>305</b> |           |
| <b>TOTAL FATAL OUTCOME REPORTS</b>                               |            | <b>14</b> |