

Drug Analysis Print
Drug name: AMISULPRIDE

[Jump to first report page](#)

| | | | |
|--------------------------------|----------------------------|------------------------|----------------|
| Drug name: | AMISULPRIDE | Report type: | Spontaneous |
| Report run date: | 15-Feb-2012 | Report origin: | UNITED KINGDOM |
| Data lock date: | 14-Feb-2012 10:30:00 PM | Route of admin: | ALL |
| Period covered: | 01-Jan-2011 to 31-Dec-2011 | Reporter type: | ALL |
| Earliest reaction date: | 01-Jan-2011 | Reaction: | ALL |
| MedDRA version: | MedDRA 14.1 | Age group: | ALL |

| | | | | | |
|------------------------------------|-----|-------------------------------------|----|---|---|
| Total number of reactions*: | 367 | Total number of ADR reports: | 73 | Total number of fatal ADR reports: | 9 |
|------------------------------------|-----|-------------------------------------|----|---|---|

| | |
|---|--------|
| Products included in this print - Single active constituent products (PBGs): | |
| SANDOZ LTD AMISULPRIDE | SOLIAN |

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| System Organ Class | Single active constituent | | Multiple active constituent | | Total unique reports* | |
|---------------------------------|---------------------------|-------|-----------------------------|-------|-----------------------|-------|
| | All | Fatal | All | Fatal | All | Fatal |
| Blood disorders | 10 | 0 | 0 | 0 | 10 | 0 |
| Cardiac disorders | 23 | 3 | 0 | 0 | 23 | 3 |
| Congenital disorders | 1 | 0 | 0 | 0 | 1 | 0 |
| Eye disorders | 1 | 0 | 0 | 0 | 1 | 0 |
| Gastrointestinal disorders | 25 | 0 | 0 | 0 | 25 | 0 |
| General disorders | 31 | 0 | 0 | 0 | 31 | 0 |
| Hepatic disorders | 1 | 0 | 0 | 0 | 1 | 0 |
| Infections | 28 | 3 | 0 | 0 | 28 | 3 |
| Injuries | 8 | 0 | 0 | 0 | 8 | 0 |
| Investigations | 84 | 0 | 0 | 0 | 84 | 0 |
| Metabolic disorders | 10 | 0 | 0 | 0 | 10 | 0 |
| Muscle & tissue disorders | 8 | 0 | 0 | 0 | 8 | 0 |
| Neoplasms | 6 | 1 | 0 | 0 | 6 | 1 |
| Nervous system disorders | 43 | 0 | 0 | 0 | 43 | 0 |
| Psychiatric disorders | 43 | 1 | 0 | 0 | 43 | 1 |
| Renal & urinary disorders | 13 | 0 | 0 | 0 | 13 | 0 |
| Reproductive & breast disorders | 2 | 0 | 0 | 0 | 2 | 0 |
| Respiratory disorders | 18 | 1 | 0 | 0 | 18 | 1 |
| Skin disorders | 2 | 0 | 0 | 0 | 2 | 0 |
| Social circumstances | 1 | 0 | 0 | 0 | 1 | 0 |
| Vascular disorders | 9 | 0 | 0 | 0 | 9 | 0 |

| | | | | | | |
|----------------------------------|------------|----------|----------|----------|------------|----------|
| TOTAL NUMBER OF REACTIONS | 367 | 9 | 0 | 0 | 367 | 9 |
|----------------------------------|------------|----------|----------|----------|------------|----------|

| | | | | | | |
|---|-----------|----------|----------|----------|------------|-----------|
| TOTAL NUMBER OF FATAL ADR REPORTS* | | 9 | | 0 | | 9* |
| TOTAL NUMBER OF ADR REPORTS* | 73 | | 0 | | 73* | |

*This provides the number of individual reports and may be less than the sum of the single-active constituent and multi-active constituent columns. For example, if both a single- and multi-active constituent product are considered by the reporter to have a suspected causal relationship with the suspected reaction, then the same report will appear in both columns.

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Glossary/Abbreviations

ADR - Adverse Drug Reaction

Age group - lists which age groups are included in the Drug Analysis Print – either ALL, Adolescent, Adult, Child, Elderly, Infant or Neonate

Data lock date - shows data on the database at this specified date and time

HLT - High Level Term - see definition of MedDRA

MedDRA - this stands for **M**edical **D**ictionary for **R**egulatory **A**ctivities, which is the internationally agreed list of terms used for Medicines Regulation. MedDRA groups related adverse drug reaction terms in a hierarchical structure whereby the '*preferred term*' (*PT*) (e.g. tunnel vision) is grouped under the broader heading the '*high level term*' (*HLT*) (e.g. visual field disorders). '*High level terms*' are contained within the '*system organ class*' (*SOC*) (e.g. eye disorders). The '*preferred term*' is the most specific term on the Drug Analysis Print, while the '*system organ class*' is the most general

Multi active constituent products - contain the drug constituent of interest plus one or more other drug constituents (e.g. co-codamol contains paracetamol and codeine)

NEC - appears in MedDRA and stands for Not Elsewhere Classified

NOS - appears in MedDRA and stands for Not Otherwise Specified

PBG - Product Brand Generic – this means drug brand name e.g. Amoxil is a PBG for the drug substance amoxicillin

Products included in this print - this is a list of the products for which at least one suspected Adverse Drug Reaction (ADR) report has been received that specifies that product as a 'suspected drug' (i.e. suspected causal association with the reaction). It does not provide an exhaustive list of the products which contain the named drug substance

PT - Preferred Term - see definition of MedDRA

Reaction - defines which ADRs are included in the Drug Analysis Print – either ALL, Serious or Non-Serious

Reporter type - lists the reporter types which are included in the Drug Analysis Print – either Patient, Health Professional or ALL (i.e. both)

Report run date - the date the Drug Analysis Print was produced

Route of admin - lists the route of administration of the suspect drug for which reports are included in the Drug Analysis Print, e.g. ORAL only includes reports where the suspect drug was specified as having been taken by the oral route, or ALL which includes all routes of administration

Spontaneous - suspected ADR reports sent in to the Yellow Card Scheme are called spontaneous reports

Single active constituent products - contain only the drug substance of interest

System Organ Class (SOC) - this is the highest level in MedDRA which groups together reactions that affect similar systems/organs in the body

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| Reaction Name | Single active constituent | | Multiple active constituent | | Total unique reports* | |
|----------------------------------|---------------------------|----------|-----------------------------|----------|-----------------------|----------|
| | All | Fatal | All | Fatal | All | Fatal |
| SOC | | | | | | |
| HLT | | | | | | |
| PT | | | | | | |
| Blood disorders | | | | | | |
| Anaemias NEC | | | | | | |
| Microcytic anaemia | 1 | 0 | 0 | 0 | 1 | 0 |
| Neutropenias | | | | | | |
| Neutropenia | 7 | 0 | 0 | 0 | 7 | 0 |
| Platelet disorders NEC | | | | | | |
| Platelet disorder | 1 | 0 | 0 | 0 | 1 | 0 |
| Thrombocytopenias | | | | | | |
| Thrombocytopenia | 1 | 0 | 0 | 0 | 1 | 0 |
| Blood disorders SOC TOTAL | 10 | 0 | 0 | 0 | 10 | 0 |

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|---|---------------------------|----------|-----------------------------|----------|-----------------------|----------|
| | All | Fatal | All | Fatal | All | Fatal |
| SOC | | | | | | |
| HLT | | | | | | |
| PT | | | | | | |
| Cardiac disorders | | | | | | |
| Coronary artery disorders NEC | | | | | | |
| Arteriosclerosis coronary artery | 2 | 1 | 0 | 0 | 2 | 1 |
| Heart failures NEC | | | | | | |
| Cardiac failure | 1 | 0 | 0 | 0 | 1 | 0 |
| Ischaemic coronary artery disorders | | | | | | |
| Myocardial infarction | 1 | 0 | 0 | 0 | 1 | 0 |
| Left ventricular failures | | | | | | |
| Left ventricular failure | 1 | 1 | 0 | 0 | 1 | 1 |
| Myocardial disorders NEC | | | | | | |
| Left ventricular hypertrophy | 1 | 0 | 0 | 0 | 1 | 0 |
| Ventricular dysfunction | 1 | 0 | 0 | 0 | 1 | 0 |
| Noninfectious myocarditis | | | | | | |
| Myocarditis | 1 | 1 | 0 | 0 | 1 | 1 |
| Rate and rhythm disorders NEC | | | | | | |
| Bradycardia | 2 | 0 | 0 | 0 | 2 | 0 |
| Tachycardia | 8 | 0 | 0 | 0 | 8 | 0 |
| Supraventricular arrhythmias | | | | | | |
| Sick sinus syndrome | 1 | 0 | 0 | 0 | 1 | 0 |
| Sinus tachycardia | 3 | 0 | 0 | 0 | 3 | 0 |
| Ventricular arrhythmias and cardiac arrest | | | | | | |
| Ventricular extrasystoles | 1 | 0 | 0 | 0 | 1 | 0 |
| Cardiac disorders SOC TOTAL | 23 | 3 | 0 | 0 | 23 | 3 |

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| Reaction Name | Single active constituent | | Multiple active constituent | | Total unique reports* | |
|---------------------------------------|---------------------------|-------|-----------------------------|-------|-----------------------|-------|
| | All | Fatal | All | Fatal | All | Fatal |
| SOC | | | | | | |
| <i>HLT</i> | | | | | | |
| PT | | | | | | |
| Congenital disorders | | | | | | |
| <i>Haemoglobinopathies congenital</i> | | | | | | |
| Sickle cell trait | 1 | 0 | 0 | 0 | 1 | 0 |
| Congenital disorders SOC TOTAL | 1 | 0 | 0 | 0 | 1 | 0 |

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| Reaction Name | Single active constituent | | Multiple active constituent | | Total unique reports* | |
|--------------------------------|---------------------------|----------|-----------------------------|----------|-----------------------|----------|
| | All | Fatal | All | Fatal | All | Fatal |
| SOC | | | | | | |
| HLT | | | | | | |
| PT | | | | | | |
| Eye disorders | | | | | | |
| Visual disorders NEC | | | | | | |
| Visual impairment | 1 | 0 | 0 | 0 | 1 | 0 |
| Eye disorders SOC TOTAL | 1 | 0 | 0 | 0 | 1 | 0 |

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| Reaction Name | Single active constituent | | Multiple active constituent | | Total unique reports* | |
|---|---------------------------|----------|-----------------------------|----------|-----------------------|----------|
| | All | Fatal | All | Fatal | All | Fatal |
| SOC | | | | | | |
| HLT | | | | | | |
| PT | | | | | | |
| Gastrointestinal disorders | | | | | | |
| <i>Acute and chronic pancreatitis</i> | | | | | | |
| Pancreatitis | 1 | 0 | 0 | 0 | 1 | 0 |
| Pancreatitis chronic | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Colitis (excl infective)</i> | | | | | | |
| Colitis | 2 | 0 | 0 | 0 | 2 | 0 |
| <i>Diarrhoea (excl infective)</i> | | | | | | |
| Diarrhoea | 3 | 0 | 0 | 0 | 3 | 0 |
| Diarrhoea haemorrhagic | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Gastric and oesophageal haemorrhages</i> | | | | | | |
| Gastric haemorrhage | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Gastric ulcers and perforation</i> | | | | | | |
| Gastric ulcer | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Gastrointestinal disorders NEC</i> | | | | | | |
| Gastric disorder | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Gastrointestinal signs and symptoms NEC</i> | | | | | | |
| Abdominal discomfort | 1 | 0 | 0 | 0 | 1 | 0 |
| Aphagia | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Gastrointestinal spastic and hypermotility disorders</i> | | | | | | |
| Irritable bowel syndrome | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Nausea and vomiting symptoms</i> | | | | | | |
| Nausea | 1 | 0 | 0 | 0 | 1 | 0 |
| Vomiting | 5 | 0 | 0 | 0 | 5 | 0 |
| <i>Oral dryness and saliva altered</i> | | | | | | |
| Salivary hypersecretion | 3 | 0 | 0 | 0 | 3 | 0 |
| <i>Peritoneal and retroperitoneal disorders</i> | | | | | | |
| Ascites | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Tooth missing</i> | | | | | | |
| Tooth loss | 1 | 0 | 0 | 0 | 1 | 0 |
| Gastrointestinal disorders SOC TOTAL | 25 | 0 | 0 | 0 | 25 | 0 |

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| Reaction Name | Single active constituent | | Multiple active constituent | | Total unique reports* | |
|--|---------------------------|----------|-----------------------------|----------|-----------------------|----------|
| | All | Fatal | All | Fatal | All | Fatal |
| SOC | | | | | | |
| HLT | | | | | | |
| PT | | | | | | |
| General disorders | | | | | | |
| <i>Asthenic conditions</i> | | | | | | |
| Asthenia | 1 | 0 | 0 | 0 | 1 | 0 |
| Malaise | 9 | 0 | 0 | 0 | 9 | 0 |
| <i>Febrile disorders</i> | | | | | | |
| Pyrexia | 2 | 0 | 0 | 0 | 2 | 0 |
| <i>Feelings and sensations NEC</i> | | | | | | |
| Feeling cold | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Fibrosis NEC</i> | | | | | | |
| Fibrosis | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Gait disturbances</i> | | | | | | |
| Gait disturbance | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>General signs and symptoms NEC</i> | | | | | | |
| Apparent death | 1 | 0 | 0 | 0 | 1 | 0 |
| General physical health deterioration | 2 | 0 | 0 | 0 | 2 | 0 |
| Influenza like illness | 1 | 0 | 0 | 0 | 1 | 0 |
| Local swelling | 1 | 0 | 0 | 0 | 1 | 0 |
| Multi-organ failure | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Interactions</i> | | | | | | |
| Drug interaction | 2 | 0 | 0 | 0 | 2 | 0 |
| <i>Oedema NEC</i> | | | | | | |
| Oedema | 1 | 0 | 0 | 0 | 1 | 0 |
| Oedema peripheral | 2 | 0 | 0 | 0 | 2 | 0 |
| <i>Pain and discomfort NEC</i> | | | | | | |
| Chest pain | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Therapeutic and nontherapeutic responses</i> | | | | | | |
| Drug ineffective | 2 | 0 | 0 | 0 | 2 | 0 |
| Drug intolerance | 1 | 0 | 0 | 0 | 1 | 0 |
| Drug resistance | 1 | 0 | 0 | 0 | 1 | 0 |
| General disorders SOC TOTAL | 31 | 0 | 0 | 0 | 31 | 0 |

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| Reaction Name | Single active constituent | | Multiple active constituent | | Total unique reports* | |
|---------------------------------------|---------------------------|-------|-----------------------------|-------|-----------------------|-------|
| | All | Fatal | All | Fatal | All | Fatal |
| SOC | | | | | | |
| <i>HLT</i> | | | | | | |
| PT | | | | | | |
| Hepatic disorders | | | | | | |
| <i>Hepatic fibrosis and cirrhosis</i> | | | | | | |
| Hepatic cirrhosis | 1 | 0 | 0 | 0 | 1 | 0 |
| Hepatic disorders SOC TOTAL | 1 | 0 | 0 | 0 | 1 | 0 |

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|--|---------------------------|----------|-----------------------------|----------|-----------------------|----------|
| | All | Fatal | All | Fatal | All | Fatal |
| SOC | | | | | | |
| HLT | | | | | | |
| PT | | | | | | |
| Infections | | | | | | |
| <i>Abdominal and gastrointestinal infections</i> | | | | | | |
| Appendicitis | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Bacterial infections NEC</i> | | | | | | |
| Cellulitis | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Escherichia infections</i> | | | | | | |
| Escherichia sepsis | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Hepatitis viral infections</i> | | | | | | |
| Hepatitis C | 2 | 0 | 0 | 0 | 2 | 0 |
| <i>Infections NEC</i> | | | | | | |
| Infection | 2 | 0 | 0 | 0 | 2 | 0 |
| Post procedural infection | 1 | 0 | 0 | 0 | 1 | 0 |
| Respiratory tract infection | 1 | 1 | 0 | 0 | 1 | 1 |
| <i>Lower respiratory tract and lung infections</i> | | | | | | |
| Bronchopneumonia | 2 | 1 | 0 | 0 | 2 | 1 |
| Lower respiratory tract infection | 6 | 0 | 0 | 0 | 6 | 0 |
| Pneumonia | 4 | 1 | 0 | 0 | 4 | 1 |
| Pneumonia primary atypical | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i> | | | | | | |
| Sepsis | 3 | 0 | 0 | 0 | 3 | 0 |
| <i>Tuberculous infections</i> | | | | | | |
| Tuberculosis | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Urinary tract infections</i> | | | | | | |
| Urinary tract infection | 2 | 0 | 0 | 0 | 2 | 0 |
| Infections SOC TOTAL | 28 | 3 | 0 | 0 | 28 | 3 |

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|--|---------------------------|----------|-----------------------------|----------|-----------------------|----------|
| | All | Fatal | All | Fatal | All | Fatal |
| SOC | | | | | | |
| <i>HLT</i> | | | | | | |
| PT | | | | | | |
| Injuries | | | | | | |
| <i>Maladministrations</i> | | | | | | |
| Drug administration error | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Medication errors NEC</i> | | | | | | |
| Medication error | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Non-site specific injuries NEC</i> | | | | | | |
| Fall | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Overdoses</i> | | | | | | |
| Intentional overdose | 1 | 0 | 0 | 0 | 1 | 0 |
| Overdose | 2 | 0 | 0 | 0 | 2 | 0 |
| <i>Skull fractures, facial bone fractures and dislocations</i> | | | | | | |
| Facial bones fracture | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Upper limb fractures and dislocations</i> | | | | | | |
| Upper limb fracture | 1 | 0 | 0 | 0 | 1 | 0 |
| Injuries SOC TOTAL | 8 | 0 | 0 | 0 | 8 | 0 |

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|---|---------------------------|-------|-----------------------------|-------|-----------------------|-------|
| | All | Fatal | All | Fatal | All | Fatal |
| SOC | | | | | | |
| HLT | | | | | | |
| PT | | | | | | |
| Investigations | | | | | | |
| <i>Blood gas and acid base analyses</i> | | | | | | |
| Oxygen saturation decreased | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Cell marker procedures</i> | | | | | | |
| Tumour marker test | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Digestive enzymes</i> | | | | | | |
| Blood amylase increased | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>ECG investigations</i> | | | | | | |
| ECG signs of myocardial ischaemia | 1 | 0 | 0 | 0 | 1 | 0 |
| Electrocardiogram QT prolonged | 3 | 0 | 0 | 0 | 3 | 0 |
| Electrocardiogram abnormal | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Heart rate and pulse investigations</i> | | | | | | |
| Heart rate increased | 2 | 0 | 0 | 0 | 2 | 0 |
| <i>Investigations NEC</i> | | | | | | |
| Quality of life decreased | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Liver function analyses</i> | | | | | | |
| Alanine aminotransferase abnormal | 1 | 0 | 0 | 0 | 1 | 0 |
| Alanine aminotransferase increased | 3 | 0 | 0 | 0 | 3 | 0 |
| Aspartate aminotransferase abnormal | 1 | 0 | 0 | 0 | 1 | 0 |
| Gamma-glutamyltransferase increased | 1 | 0 | 0 | 0 | 1 | 0 |
| Liver function test abnormal | 2 | 0 | 0 | 0 | 2 | 0 |
| <i>Neurologic diagnostic procedures</i> | | | | | | |
| Coma scale abnormal | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Physical examination procedures</i> | | | | | | |
| Body temperature increased | 1 | 0 | 0 | 0 | 1 | 0 |
| Weight decreased | 1 | 0 | 0 | 0 | 1 | 0 |
| Weight increased | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Pituitary analyses anterior</i> | | | | | | |
| Blood prolactin increased | 3 | 0 | 0 | 0 | 3 | 0 |
| <i>Platelet analyses</i> | | | | | | |
| Platelet count decreased | 3 | 0 | 0 | 0 | 3 | 0 |
| Platelet count increased | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Protein analyses NEC</i> | | | | | | |
| C-reactive protein increased | 2 | 0 | 0 | 0 | 2 | 0 |
| <i>Red blood cell analyses</i> | | | | | | |
| Haematocrit decreased | 1 | 0 | 0 | 0 | 1 | 0 |
| Haemoglobin decreased | 6 | 0 | 0 | 0 | 6 | 0 |
| Mean cell haemoglobin concentration increased | 1 | 0 | 0 | 0 | 1 | 0 |
| Red blood cell count decreased | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Renal function analyses</i> | | | | | | |
| Blood creatinine increased | 1 | 0 | 0 | 0 | 1 | 0 |
| Blood urea decreased | 1 | 0 | 0 | 0 | 1 | 0 |

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Drug Analysis Print

Drug name: AMISULPRIDE

| | | | |
|-------------------------|----------------------------|-----------------|----------------|
| Drug name: | AMISULPRIDE | Report type: | Spontaneous |
| Report run date: | 15-Feb-2012 | Report origin: | UNITED KINGDOM |
| Data lock date: | 14-Feb-2012 10:30:00 PM | Route of admin: | ALL |
| Period covered: | 01-Jan-2011 to 31-Dec-2011 | Reporter type: | ALL |
| Earliest reaction date: | 01-Jan-2011 | Reaction: | ALL |
| MedDRA version: | MedDRA 14.1 | Age group: | ALL |

| Reaction Name Investigations cont'd | Single active constituent | | Multiple active constituent | | Total unique reports* | |
|---|---------------------------|----------|-----------------------------|----------|-----------------------|----------|
| | All | Fatal | All | Fatal | All | Fatal |
| SOC | | | | | | |
| HLT | | | | | | |
| PT | | | | | | |
| Blood urea increased | 2 | 0 | 0 | 0 | 2 | 0 |
| Skeletal and cardiac muscle analyses | | | | | | |
| Blood creatine phosphokinase increased | 6 | 0 | 0 | 0 | 6 | 0 |
| Troponin T increased | 1 | 0 | 0 | 0 | 1 | 0 |
| Therapeutic drug monitoring analyses | | | | | | |
| Antipsychotic drug level above therapeutic | 1 | 0 | 0 | 0 | 1 | 0 |
| Antipsychotic drug level below therapeutic | 1 | 0 | 0 | 0 | 1 | 0 |
| Antipsychotic drug level increased | 4 | 0 | 0 | 0 | 4 | 0 |
| Drug level above therapeutic | 1 | 0 | 0 | 0 | 1 | 0 |
| Tissue enzyme analyses NEC | | | | | | |
| Blood alkaline phosphatase increased | 3 | 0 | 0 | 0 | 3 | 0 |
| Vascular tests NEC (incl blood pressure) | | | | | | |
| Blood pressure decreased | 1 | 0 | 0 | 0 | 1 | 0 |
| Blood pressure increased | 1 | 0 | 0 | 0 | 1 | 0 |
| White blood cell analyses | | | | | | |
| Differential white blood cell count abnormal | 2 | 0 | 0 | 0 | 2 | 0 |
| Eosinophil count increased | 2 | 0 | 0 | 0 | 2 | 0 |
| Neutrophil count abnormal | 1 | 0 | 0 | 0 | 1 | 0 |
| Neutrophil count decreased | 5 | 0 | 0 | 0 | 5 | 0 |
| Neutrophil count increased | 2 | 0 | 0 | 0 | 2 | 0 |
| White blood cell count decreased | 6 | 0 | 0 | 0 | 6 | 0 |
| White blood cell count increased | 2 | 0 | 0 | 0 | 2 | 0 |
| Investigations SOC TOTAL | 84 | 0 | 0 | 0 | 84 | 0 |

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Drug Analysis Print
Drug name: AMISULPRIDE

| | | | |
|-------------------------|----------------------------|-----------------|----------------|
| Drug name: | AMISULPRIDE | Report type: | Spontaneous |
| Report run date: | 15-Feb-2012 | Report origin: | UNITED KINGDOM |
| Data lock date: | 14-Feb-2012 10:30:00 PM | Route of admin: | ALL |
| Period covered: | 01-Jan-2011 to 31-Dec-2011 | Reporter type: | ALL |
| Earliest reaction date: | 01-Jan-2011 | Reaction: | ALL |
| MedDRA version: | MedDRA 14.1 | Age group: | ALL |

| Reaction Name | Single active constituent | | Multiple active constituent | | Total unique reports* | |
|---|---------------------------|----------|-----------------------------|----------|-----------------------|----------|
| | All | Fatal | All | Fatal | All | Fatal |
| SOC | | | | | | |
| HLT | | | | | | |
| PT | | | | | | |
| Metabolic disorders | | | | | | |
| <i>Appetite disorders</i> | | | | | | |
| Hypophagia | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Diabetes mellitus (incl subtypes)</i> | | | | | | |
| Diabetes mellitus | 3 | 0 | 0 | 0 | 3 | 0 |
| <i>General nutritional disorders NEC</i> | | | | | | |
| Obesity | 1 | 0 | 0 | 0 | 1 | 0 |
| Overweight | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Sodium imbalance</i> | | | | | | |
| Hyponatraemia | 3 | 0 | 0 | 0 | 3 | 0 |
| <i>Total fluid volume decreased</i> | | | | | | |
| Dehydration | 1 | 0 | 0 | 0 | 1 | 0 |
| Metabolic disorders SOC TOTAL | 10 | 0 | 0 | 0 | 10 | 0 |

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Drug Analysis Print
Drug name: AMISULPRIDE

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|-------------------------|----------------------------|-----------------|----------------|
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| Reaction Name | Single active constituent | | Multiple active constituent | | Total unique reports* | |
|---|---------------------------|----------|-----------------------------|----------|-----------------------|----------|
| | All | Fatal | All | Fatal | All | Fatal |
| SOC | | | | | | |
| HLT | | | | | | |
| PT | | | | | | |
| Muscle & tissue disorders | | | | | | |
| Arthropathies NEC | | | | | | |
| Arthritis | 1 | 0 | 0 | 0 | 1 | 0 |
| Lupus erythematosus (incl subtypes) | | | | | | |
| Systemic lupus erythematosus | 1 | 0 | 0 | 0 | 1 | 0 |
| Muscle tone abnormalities | | | | | | |
| Muscle rigidity | 1 | 0 | 0 | 0 | 1 | 0 |
| Musculoskeletal and connective tissue signs and symptoms NEC | | | | | | |
| Mobility decreased | 2 | 0 | 0 | 0 | 2 | 0 |
| Posture abnormal | 1 | 0 | 0 | 0 | 1 | 0 |
| Myopathies | | | | | | |
| Rhabdomyolysis | 2 | 0 | 0 | 0 | 2 | 0 |
| Muscle & tissue disorders SOC TOTAL | 8 | 0 | 0 | 0 | 8 | 0 |

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Drug Analysis Print
Drug name: AMISULPRIDE

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|-------------------------|----------------------------|-----------------|----------------|
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| Period covered: | 01-Jan-2011 to 31-Dec-2011 | Reporter type: | ALL |
| Earliest reaction date: | 01-Jan-2011 | Reaction: | ALL |
| MedDRA version: | MedDRA 14.1 | Age group: | ALL |

| Reaction Name | Single active constituent | | Multiple active constituent | | Total unique reports* | |
|--|---------------------------|----------|-----------------------------|----------|-----------------------|----------|
| | All | Fatal | All | Fatal | All | Fatal |
| SOC | | | | | | |
| HLT | | | | | | |
| PT | | | | | | |
| Neoplasms | | | | | | |
| <i>Neoplasms malignant site unspecified NEC</i> | | | | | | |
| Neoplasm malignant | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i> | | | | | | |
| Lung neoplasm malignant | 1 | 1 | 0 | 0 | 1 | 1 |
| <i>Respiratory tract small cell carcinomas</i> | | | | | | |
| Small cell lung cancer stage unspecified | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Testicular neoplasms malignant</i> | | | | | | |
| Testis cancer | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Urinary tract neoplasms unspecified malignancy NEC</i> | | | | | | |
| Bladder neoplasm | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Uterine neoplasms benign</i> | | | | | | |
| Uterine leiomyoma | 1 | 0 | 0 | 0 | 1 | 0 |
| Neoplasms SOC TOTAL | 6 | 1 | 0 | 0 | 6 | 1 |

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Drug Analysis Print
Drug name: AMISULPRIDE

| | | | |
|-------------------------|----------------------------|-----------------|----------------|
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| MedDRA version: | MedDRA 14.1 | Age group: | ALL |

| Reaction Name | Single active constituent | | Multiple active constituent | | Total unique reports* | |
|--|---------------------------|----------|-----------------------------|----------|-----------------------|----------|
| | All | Fatal | All | Fatal | All | Fatal |
| SOC | | | | | | |
| HLT | | | | | | |
| PT | | | | | | |
| Nervous system disorders | | | | | | |
| <i>Central nervous system vascular disorders NEC</i> | | | | | | |
| Cerebral arteriosclerosis | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Cerebellar coordination and balance disturbances</i> | | | | | | |
| Dysstasia | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Disturbances in consciousness NEC</i> | | | | | | |
| Depressed level of consciousness | 1 | 0 | 0 | 0 | 1 | 0 |
| Loss of consciousness | 1 | 0 | 0 | 0 | 1 | 0 |
| Sedation | 6 | 0 | 0 | 0 | 6 | 0 |
| Syncope | 2 | 0 | 0 | 0 | 2 | 0 |
| <i>Dyskinesias and movement disorders NEC</i> | | | | | | |
| Movement disorder | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Dystonias</i> | | | | | | |
| Dystonia | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Memory loss (excl dementia)</i> | | | | | | |
| Memory impairment | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Mental impairment (excl dementia and memory loss)</i> | | | | | | |
| Disturbance in attention | 2 | 0 | 0 | 0 | 2 | 0 |
| Mental impairment | 7 | 0 | 0 | 0 | 7 | 0 |
| <i>Muscle tone abnormal</i> | | | | | | |
| Neuroleptic malignant syndrome | 5 | 0 | 0 | 0 | 5 | 0 |
| <i>Narcolepsy and hypersomnia</i> | | | | | | |
| Hypersomnia | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Neurological signs and symptoms NEC</i> | | | | | | |
| Dizziness | 4 | 0 | 0 | 0 | 4 | 0 |
| <i>Parkinson's disease and parkinsonism</i> | | | | | | |
| Parkinson's disease | 1 | 0 | 0 | 0 | 1 | 0 |
| Parkinsonism | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Seizures and seizure disorders NEC</i> | | | | | | |
| Convulsion | 3 | 0 | 0 | 0 | 3 | 0 |
| Epilepsy | 1 | 0 | 0 | 0 | 1 | 0 |
| Status epilepticus | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Sensory abnormalities NEC</i> | | | | | | |
| Hypoaesthesia | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Speech and language abnormalities</i> | | | | | | |
| Speech disorder | 1 | 0 | 0 | 0 | 1 | 0 |
| Nervous system disorders SOC TOTAL | 43 | 0 | 0 | 0 | 43 | 0 |

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Drug Analysis Print
Drug name: AMISULPRIDE

| | | | |
|--------------------------------|----------------------------|------------------------|----------------|
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| MedDRA version: | MedDRA 14.1 | Age group: | ALL |

| Reaction Name | Single active constituent | | Multiple active constituent | | Total unique reports* | |
|--|---------------------------|-------|-----------------------------|-------|-----------------------|-------|
| | All | Fatal | All | Fatal | All | Fatal |
| SOC | | | | | | |
| HLT | | | | | | |
| PT | | | | | | |
| Psychiatric disorders | | | | | | |
| Abnormal behaviour NEC | | | | | | |
| Abnormal behaviour | 2 | 0 | 0 | 0 | 2 | 0 |
| Abnormal food elimination | | | | | | |
| Self-induced vomiting | 1 | 0 | 0 | 0 | 1 | 0 |
| Anxiety symptoms | | | | | | |
| Anxiety | 2 | 0 | 0 | 0 | 2 | 0 |
| Nervousness | 1 | 0 | 0 | 0 | 1 | 0 |
| Behaviour and socialisation disturbances | | | | | | |
| Paranoia | 2 | 0 | 0 | 0 | 2 | 0 |
| Communications disorders | | | | | | |
| Mutism | 1 | 0 | 0 | 0 | 1 | 0 |
| Confusion and disorientation | | | | | | |
| Confusional state | 2 | 0 | 0 | 0 | 2 | 0 |
| Delusional symptoms | | | | | | |
| Delusion | 2 | 0 | 0 | 0 | 2 | 0 |
| Delusion of reference | 1 | 0 | 0 | 0 | 1 | 0 |
| Mental disorders NEC | | | | | | |
| Mental disorder | 2 | 0 | 0 | 0 | 2 | 0 |
| Mood alterations with depressive symptoms | | | | | | |
| Depressed mood | 2 | 0 | 0 | 0 | 2 | 0 |
| Panic attacks and disorders | | | | | | |
| Panic attack | 1 | 0 | 0 | 0 | 1 | 0 |
| Perception disturbances | | | | | | |
| Hallucination | 1 | 0 | 0 | 0 | 1 | 0 |
| Hallucination, auditory | 4 | 0 | 0 | 0 | 4 | 0 |
| Hallucination, visual | 1 | 0 | 0 | 0 | 1 | 0 |
| Illusion | 1 | 0 | 0 | 0 | 1 | 0 |
| Psychiatric symptoms NEC | | | | | | |
| Impaired self-care | 1 | 0 | 0 | 0 | 1 | 0 |
| Psychotic disorder NEC | | | | | | |
| Psychotic disorder | 5 | 0 | 0 | 0 | 5 | 0 |
| Schizophrenia NEC | | | | | | |
| Schizophrenia | 4 | 0 | 0 | 0 | 4 | 0 |
| Schizophrenia, catatonic type | 1 | 0 | 0 | 0 | 1 | 0 |
| Schizophrenia, paranoid type | 1 | 0 | 0 | 0 | 1 | 0 |
| Stereotypies and automatisms | | | | | | |
| Posturing | 1 | 0 | 0 | 0 | 1 | 0 |
| Waxy flexibility | 1 | 0 | 0 | 0 | 1 | 0 |
| Substance-related disorders | | | | | | |
| Substance abuse | 1 | 0 | 0 | 0 | 1 | 0 |
| Suicidal and self-injurious behaviour | | | | | | |

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Drug Analysis Print

Drug name: AMISULPRIDE

| | | | |
|-------------------------|----------------------------|-----------------|----------------|
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| MedDRA version: | MedDRA 14.1 | Age group: | ALL |

| Reaction Name | Single active constituent | | Multiple active constituent | | Total unique reports* | |
|---------------------------------|---------------------------|-------|-----------------------------|-------|-----------------------|-------|
| | All | Fatal | All | Fatal | All | Fatal |
| Psychiatric disorders cont'd | | | | | | |
| SOC | | | | | | |
| HLT | | | | | | |
| PT | | | | | | |
| Completed suicide | 1 | 1 | 0 | 0 | 1 | 1 |
| Suicide attempt | 1 | 0 | 0 | 0 | 1 | 0 |
| Psychiatric disorders SOC TOTAL | 43 | 1 | 0 | 0 | 43 | 1 |

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Drug Analysis Print
Drug name: AMISULPRIDE

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| Reaction Name | Single active constituent | | Multiple active constituent | | Total unique reports* | |
|--|---------------------------|----------|-----------------------------|----------|-----------------------|----------|
| | All | Fatal | All | Fatal | All | Fatal |
| SOC | | | | | | |
| <i>HLT</i> | | | | | | |
| PT | | | | | | |
| Renal & urinary disorders | | | | | | |
| <i>Bladder and urethral symptoms</i> | | | | | | |
| Pollakiuria | 1 | 0 | 0 | 0 | 1 | 0 |
| Urinary incontinence | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Bladder disorders NEC</i> | | | | | | |
| Bladder obstruction | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Genital and urinary tract disorders NEC</i> | | | | | | |
| Urinary tract obstruction | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Nephritis NEC</i> | | | | | | |
| Nephritis | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Renal disorders NEC</i> | | | | | | |
| Renal disorder | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Renal failure and impairment</i> | | | | | | |
| Renal failure | 1 | 0 | 0 | 0 | 1 | 0 |
| Renal failure acute | 2 | 0 | 0 | 0 | 2 | 0 |
| Renal failure chronic | 1 | 0 | 0 | 0 | 1 | 0 |
| Renal impairment | 2 | 0 | 0 | 0 | 2 | 0 |
| <i>Urinary tract signs and symptoms NEC</i> | | | | | | |
| Nocturia | 1 | 0 | 0 | 0 | 1 | 0 |
| Renal & urinary disorders SOC TOTAL | 13 | 0 | 0 | 0 | 13 | 0 |

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| MedDRA version: | MedDRA 14.1 | Age group: | ALL |

| Reaction Name | Single active constituent | | Multiple active constituent | | Total unique reports* | |
|--|---------------------------|----------|-----------------------------|----------|-----------------------|----------|
| | All | Fatal | All | Fatal | All | Fatal |
| SOC | | | | | | |
| HLT | | | | | | |
| PT | | | | | | |
| Reproductive & breast disorders | | | | | | |
| Breast signs and symptoms | | | | | | |
| Breast tenderness | 1 | 0 | 0 | 0 | 1 | 0 |
| Menstruation with increased bleeding | | | | | | |
| Menorrhagia | 1 | 0 | 0 | 0 | 1 | 0 |
| Reproductive & breast disorders SOC TOTAL | 2 | 0 | 0 | 0 | 2 | 0 |

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| Reaction Name | Single active constituent | | Multiple active constituent | | Total unique reports* | |
|--|---------------------------|----------|-----------------------------|----------|-----------------------|----------|
| | All | Fatal | All | Fatal | All | Fatal |
| SOC | | | | | | |
| HLT | | | | | | |
| PT | | | | | | |
| Respiratory disorders | | | | | | |
| <i>Breathing abnormalities</i> | | | | | | |
| Dyspnoea | 4 | 0 | 0 | 0 | 4 | 0 |
| Respiratory arrest | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Bronchospasm and obstruction</i> | | | | | | |
| Chronic obstructive pulmonary disease | 1 | 0 | 0 | 0 | 1 | 0 |
| Wheezing | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Coughing and associated symptoms</i> | | | | | | |
| Cough | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Parenchymal lung disorders NEC</i> | | | | | | |
| Lung consolidation | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Pneumothorax and pleural effusions NEC</i> | | | | | | |
| Pleural effusion | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Pulmonary oedemas</i> | | | | | | |
| Pulmonary oedema | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Pulmonary thrombotic and embolic conditions</i> | | | | | | |
| Pulmonary embolism | 3 | 1 | 0 | 0 | 3 | 1 |
| <i>Respiratory failures (excl neonatal)</i> | | | | | | |
| Respiratory failure | 2 | 0 | 0 | 0 | 2 | 0 |
| <i>Respiratory tract disorders NEC</i> | | | | | | |
| Lung disorder | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Upper respiratory tract signs and symptoms</i> | | | | | | |
| Choking | 1 | 0 | 0 | 0 | 1 | 0 |
| Respiratory disorders SOC TOTAL | 18 | 1 | 0 | 0 | 18 | 1 |

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| Earliest reaction date: | 01-Jan-2011 | Reaction: | ALL |
| MedDRA version: | MedDRA 14.1 | Age group: | ALL |

| Reaction Name | Single active constituent | | Multiple active constituent | | Total unique reports* | |
|---|---------------------------|-------|-----------------------------|-------|-----------------------|-------|
| | All | Fatal | All | Fatal | All | Fatal |
| SOC | | | | | | |
| <i>HLT</i> | | | | | | |
| PT | | | | | | |
| Skin disorders | | | | | | |
| <i>Apocrine and eccrine gland disorders</i> | | | | | | |
| Hyperhidrosis | 2 | 0 | 0 | 0 | 2 | 0 |
| Skin disorders SOC TOTAL | 2 | 0 | 0 | 0 | 2 | 0 |

*This provides the number of individual reports and may be less than the sum of the single-active constituent and multi-active constituent columns. For example, if both a single- and multi-active constituent product are considered by the reporter to have a suspected causal relationship with the suspected reaction, then the same report will appear in both columns.

Drug Analysis Print

Drug name: AMISULPRIDE

| | | | |
|-------------------------|----------------------------|-----------------|----------------|
| Drug name: | AMISULPRIDE | Report type: | Spontaneous |
| Report run date: | 15-Feb-2012 | Report origin: | UNITED KINGDOM |
| Data lock date: | 14-Feb-2012 10:30:00 PM | Route of admin: | ALL |
| Period covered: | 01-Jan-2011 to 31-Dec-2011 | Reporter type: | ALL |
| Earliest reaction date: | 01-Jan-2011 | Reaction: | ALL |
| MedDRA version: | MedDRA 14.1 | Age group: | ALL |

| Reaction Name | Single active constituent | | Multiple active constituent | | Total unique reports* | |
|--------------------------------|---------------------------|-------|-----------------------------|-------|-----------------------|-------|
| | All | Fatal | All | Fatal | All | Fatal |
| SOC | | | | | | |
| <i>HLT</i> | | | | | | |
| PT | | | | | | |
| Social circumstances | | | | | | |
| <i>Disability issues</i> | | | | | | |
| Bedridden | 1 | 0 | 0 | 0 | 1 | 0 |
| Social circumstances SOC TOTAL | 1 | 0 | 0 | 0 | 1 | 0 |

*This provides the number of individual reports and may be less than the sum of the single-active constituent and multi-active constituent columns. For example, if both a single- and multi-active constituent product are considered by the reporter to have a suspected causal relationship with the suspected reaction, then the same report will appear in both columns.

Drug Analysis Print
Drug name: AMISULPRIDE

| | | | |
|--------------------------------|----------------------------|------------------------|----------------|
| Drug name: | AMISULPRIDE | Report type: | Spontaneous |
| Report run date: | 15-Feb-2012 | Report origin: | UNITED KINGDOM |
| Data lock date: | 14-Feb-2012 10:30:00 PM | Route of admin: | ALL |
| Period covered: | 01-Jan-2011 to 31-Dec-2011 | Reporter type: | ALL |
| Earliest reaction date: | 01-Jan-2011 | Reaction: | ALL |
| MedDRA version: | MedDRA 14.1 | Age group: | ALL |

| Reaction Name | Single active constituent | | Multiple active constituent | | Total unique reports* | |
|--|---------------------------|----------|-----------------------------|----------|-----------------------|----------|
| | All | Fatal | All | Fatal | All | Fatal |
| SOC | | | | | | |
| HLT | | | | | | |
| PT | | | | | | |
| Vascular disorders | | | | | | |
| <i>Blood pressure disorders NEC</i> | | | | | | |
| Blood pressure fluctuation | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Circulatory collapse and shock</i> | | | | | | |
| Circulatory collapse | 2 | 0 | 0 | 0 | 2 | 0 |
| <i>Haemorrhages NEC</i> | | | | | | |
| Haemorrhage | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Peripheral embolism and thrombosis</i> | | | | | | |
| Deep vein thrombosis | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Peripheral vascular disorders NEC</i> | | | | | | |
| Peripheral vascular disorder | 1 | 0 | 0 | 0 | 1 | 0 |
| <i>Vascular hypertensive disorders NEC</i> | | | | | | |
| Hypertension | 3 | 0 | 0 | 0 | 3 | 0 |
| Vascular disorders SOC TOTAL | 9 | 0 | 0 | 0 | 9 | 0 |

| | | | | | | |
|----------------------------------|------------|----------|----------|----------|------------|----------|
| TOTAL NUMBER OF REACTIONS | 367 | 9 | 0 | 0 | 367 | 9 |
|----------------------------------|------------|----------|----------|----------|------------|----------|

| | | | | | | |
|---|-----------|----------|----------|----------|------------|-----------|
| TOTAL NUMBER OF FATAL ADR REPORTS* | | 9 | | 0 | | 9* |
| TOTAL NUMBER OF ADR REPORTS* | 73 | | 0 | | 73* | |

*This provides the number of individual reports and may be less than the sum of the single-active constituent and multi-active constituent columns. For example, if both a single- and multi-active constituent product are considered by the reporter to have a suspected causal relationship with the suspected reaction, then the same report will appear in both columns.