



Australian Government

Department of Health

Therapeutic Goods Administration

Database of Adverse Event Notifications - medicines

Medicine summary

You searched for the following **2 medicines** between **01/01/2000 – 18/10/2017**:

- Invokana (Canagliflozin)
- Not specified (Canagliflozin)

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Important information

The TGA uses adverse event reports to identify when a safety issue may be present. An adverse event report does not mean that the medicine is the cause of the adverse event. If you are experiencing an adverse event, or think you may be experiencing one, please seek advice from a health professional as soon as possible. The TGA strongly advises people taking prescription medicines not to change their medication regime without prior consultation with a health professional.

About the Database of Adverse Event Notifications (DAEN) - medicines

- The DAEN - medicines contains information from reports of adverse events that the TGA has received in relation to medicines including vaccines used in Australia.
- The DAEN - medicines does not contain all known safety information about a particular medicine. Please do not make an assessment about the safety of a medicine based on the information in the DAEN - medicines.

The TGA medicine safety monitoring program

More information about the DAEN - medicines and the TGA medicines safety monitoring program is available at:

- About the DAEN - medicines <<http://www.tga.gov.au/safety/daen-about.htm>>
- Medicines safety <<http://www.tga.gov.au/safety/information-medicines.htm>>

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Other useful sources of information on Australian medicines

More information about a medicine is available from the Product Information (PI) <<http://www.tga.gov.au/hp/information-medicines-pi.htm>> and Consumer Medicine Information (CMI) <<http://www.tga.gov.au/consumers/information-medicines-cmi.htm>> leaflet or the labelling of the medicine. Australian Public Assessment Report for Prescription Medicines (AusPARs) <<http://www.tga.gov.au/industry/pm-auspar.htm>> for some prescription medicines, are also available from the TGA website. <<http://www.tga.gov.au>>
Your health professional can also provide help and assistance on how to use medicines.
Information on medicines used in Australia is available from NPS MedicineWise <<http://www.nps.org.au/>>.

About the release of this information

While reasonable care is taken to ensure that the information is an accurate record of the adverse events reported to the TGA, the TGA does not guarantee or warrant the accuracy, reliability, completeness or currency of the information or its usefulness in achieving any purpose.

To the fullest extent permitted by law, including but not limited to section 61A of the Therapeutic Goods Act 1989, the TGA will not be liable for any loss, damage, cost or expense incurred in or arising by reason of any person relying on this information.

Copyright restrictions apply to the DAEN - medicines <<http://www.tga.gov.au/about/website-copyright.htm>>.

Results

Number of reports (cases): 27

(Multiple adverse events have been reported for some patients)

Number of cases with a single suspected medicine: 26

(The TGA thinks there is a possibility that the medicine caused the adverse event)

Number of cases where death was a reported outcome: 1

(These reports of death may or may not have been a result of taking a medicine)

| MedDRA system organ class ⁱ | MedDRA reaction term ⁱⁱ | Number of cases ⁱⁱⁱ | Number of cases with a single suspected medicine ^{iv} | Number of cases where death was a reported outcome ^v |
|--|--|--------------------------------|--|---|
| Metabolism and nutrition disorders | Dehydration | 2 | 2 | 0 |
| Metabolism and nutrition disorders | Diabetic ketoacidosis | 2 | 2 | 0 |
| Investigations | Glomerular filtration rate decreased | 2 | 2 | 0 |
| Cardiac disorders | Myocardial infarction | 2 | 2 | 0 |
| Metabolism and nutrition disorders | Ketoacidosis | 2 | 1 | 0 |
| Renal and urinary disorders | Renal failure | 2 | 2 | 0 |
| Investigations | Weight decreased | 2 | 2 | 0 |
| Cardiac disorders | Tachycardia | 2 | 1 | 0 |
| General disorders and administration site conditions | Thirst | 1 | 1 | 0 |
| Infections and infestations | Urinary tract infection | 1 | 1 | 0 |
| Ear and labyrinth disorders | Vertigo | 1 | 1 | 0 |
| Infections and infestations | Vulvovaginal candidiasis | 1 | 1 | 0 |
| Injury, poisoning and procedural complications | Off label use | 1 | 1 | 0 |
| Nervous system disorders | Cognitive disorder | 1 | 1 | 0 |
| Investigations | Urine output increased | 1 | 1 | 0 |
| Injury, poisoning and procedural complications | Incorrect dose administered | 1 | 1 | 0 |
| Renal and urinary disorders | Acute kidney injury | 1 | 1 | 0 |
| Infections and infestations | Candida infection | 1 | 1 | 0 |
| Injury, poisoning and procedural complications | Wrong technique in product usage process | 1 | 1 | 0 |
| Musculoskeletal and connective tissue disorders | Rhabdomyolysis | 1 | 1 | 0 |
| Nervous system disorders | Somnolence | 1 | 1 | 0 |
| Nervous system disorders | Syncope | 1 | 1 | 0 |
| Nervous system disorders | Lethargy | 1 | 1 | 0 |
| Investigations | Liver function test abnormal | 1 | 1 | 0 |
| Nervous system disorders | Loss of consciousness | 1 | 1 | 0 |

| MedDRA system organ class ⁱ | MedDRA reaction term ⁱⁱ | Number of cases ⁱⁱⁱ | Number of cases with a single suspected medicine ^{iv} | Number of cases where death was a reported outcome ^v |
|---|------------------------------------|--------------------------------|--|---|
| General disorders and administration site conditions | Malaise | 1 | 1 | 0 |
| Gastrointestinal disorders | Nausea | 1 | 1 | 0 |
| Renal and urinary disorders | Nephrogenic diabetes insipidus | 1 | 1 | 0 |
| Renal and urinary disorders | Nocturia | 1 | 1 | 0 |
| Infections and infestations | Oral candidiasis | 1 | 1 | 0 |
| Renal and urinary disorders | Pollakiuria | 1 | 1 | 0 |
| Skin and subcutaneous tissue disorders | Rash pruritic | 1 | 1 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | Renal cancer | 1 | 1 | 0 |
| Nervous system disorders | Headache | 1 | 1 | 0 |
| Skin and subcutaneous tissue disorders | Hyperhidrosis | 1 | 1 | 0 |
| Nervous system disorders | Hypoglycaemic coma | 1 | 1 | 1 |
| Nervous system disorders | Disturbance in attention | 1 | 1 | 0 |
| General disorders and administration site conditions | Drug ineffective | 1 | 1 | 0 |
| Respiratory, thoracic and mediastinal disorders | Dyspnoea | 1 | 0 | 0 |
| Cardiac disorders | Angina unstable | 1 | 1 | 0 |
| Musculoskeletal and connective tissue disorders | Back pain | 1 | 0 | 0 |
| Reproductive system and breast disorders | Balanoposthitis | 1 | 1 | 0 |
| Investigations | Blood glucose increased | 1 | 1 | 0 |
| Investigations | Blood potassium decreased | 1 | 1 | 0 |
| Investigations | Blood pressure increased | 1 | 1 | 0 |
| Cardiac disorders | Cardiac arrest | 1 | 1 | 1 |
| General disorders and administration site conditions | Concomitant disease aggravated | 1 | 1 | 0 |

Footnotes

ⁱ A description of what, in general terms, was affected by the adverse event, as described by the Medical Dictionary for Regulatory Activities MedDRA (for example 'cardiac disorders')

ⁱⁱ A description of the adverse event as defined by MedDRA; these adverse events are grouped by system organ class. You can use the MedlinePlus medical dictionary <<http://www.nlm.nih.gov/medlineplus/mplusdictionary.html>> to look up terms.

ⁱⁱⁱ The number of cases for which each type of adverse event was reported

^{iv} Results show where a medicine is the only medicine suspected to be related to the adverse event

∨ These reports of death may or may not have been the result of taking a medicine



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Medicine summary

You searched for the following **3 medicines** between **01/01/2000 – 18/10/2017**:

- Dapagliflozin (Dapagliflozin)
- Forxiga (Dapagliflozin)
- Xigduo XR (Dapagliflozin-Metformin)

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Results

Number of reports (cases): 209

(Multiple adverse events have been reported for some patients)

Number of cases with a single suspected medicine: 178

(The TGA thinks there is a possibility that the medicine caused the adverse event)

Number of cases where death was a reported outcome: 1

(These reports of death may or may not have been a result of taking a medicine)

| MedDRA system organ class ⁱ | MedDRA reaction term ⁱⁱ | Number of cases ⁱⁱⁱ | Number of cases with a single suspected medicine ^{iv} | Number of cases where death was a reported outcome ^v |
|---|--------------------------------------|--------------------------------|--|---|
| Metabolism and nutrition disorders | Diabetic ketoacidosis | 60 | 50 | 0 |
| Metabolism and nutrition disorders | Ketoacidosis | 13 | 11 | 0 |
| Infections and infestations | Urinary tract infection | 12 | 11 | 1 |
| Gastrointestinal disorders | Nausea | 8 | 6 | 0 |
| Investigations | Glomerular filtration rate decreased | 7 | 5 | 0 |
| Injury, poisoning and procedural complications | Off label use | 7 | 5 | 0 |
| Renal and urinary disorders | Renal impairment | 7 | 7 | 0 |
| Renal and urinary disorders | Acute kidney injury | 7 | 6 | 1 |
| Skin and subcutaneous tissue disorders | Rash | 7 | 7 | 0 |
| Gastrointestinal disorders | Vomiting | 6 | 5 | 0 |
| Metabolism and nutrition disorders | Dehydration | 6 | 5 | 0 |
| Nervous system disorders | Dizziness | 5 | 3 | 0 |
| Infections and infestations | Pyelonephritis | 5 | 5 | 0 |
| Infections and infestations | Candida infection | 5 | 4 | 0 |
| Infections and infestations | Urosepsis | 4 | 4 | 0 |
| Investigations | Weight decreased | 4 | 3 | 0 |
| Nervous system disorders | Headache | 4 | 4 | 0 |
| Renal and urinary disorders | Haematuria | 4 | 4 | 0 |
| Metabolism and nutrition disorders | Hyperglycaemia | 3 | 3 | 0 |
| General disorders and administration site conditions | Fatigue | 3 | 1 | 0 |
| Infections and infestations | Necrotising fasciitis | 3 | 3 | 0 |
| General disorders and administration site conditions | Drug ineffective | 3 | 3 | 0 |
| Musculoskeletal and connective tissue disorders | Back pain | 3 | 2 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | Bladder cancer | 3 | 3 | 0 |

| MedDRA system organ class ⁱ | MedDRA reaction term ⁱⁱ | Number of cases ⁱⁱⁱ | Number of cases with a single suspected medicine ^{iv} | Number of cases where death was a reported outcome ^v |
|--|---|--------------------------------|--|---|
| Infections and infestations | Vulvovaginal candidiasis | 3 | 3 | 0 |
| Musculoskeletal and connective tissue disorders | Myalgia | 3 | 3 | 0 |
| Renal and urinary disorders | Pollakiuria | 3 | 3 | 0 |
| Renal and urinary disorders | Renal failure | 3 | 3 | 0 |
| Injury, poisoning and procedural complications | Product use issue | 3 | 3 | 0 |
| Investigations | Liver function test increased | 2 | 2 | 0 |
| Skin and subcutaneous tissue disorders | Rash pruritic | 2 | 2 | 0 |
| Infections and infestations | Sepsis | 2 | 2 | 0 |
| Nervous system disorders | Syncope | 2 | 1 | 0 |
| Injury, poisoning and procedural complications | Fall | 2 | 2 | 0 |
| General disorders and administration site conditions | Malaise | 2 | 2 | 0 |
| Gastrointestinal disorders | Pancreatitis | 2 | 2 | 0 |
| Skin and subcutaneous tissue disorders | Urticaria | 2 | 2 | 0 |
| Metabolism and nutrition disorders | Hyperglycaemic hyperosmolar nonketotic syndrome | 2 | 2 | 0 |
| Investigations | Blood ketone body increased | 2 | 2 | 0 |
| Reproductive system and breast disorders | Balanoposthitis | 2 | 1 | 0 |
| Gastrointestinal disorders | Abdominal pain | 2 | 2 | 0 |
| Metabolism and nutrition disorders | Acidosis | 2 | 2 | 0 |
| Skin and subcutaneous tissue disorders | Alopecia | 2 | 2 | 0 |
| Investigations | Anion gap increased | 2 | 1 | 0 |
| Investigations | Blood glucose increased | 2 | 2 | 0 |
| Metabolism and nutrition disorders | Ketosis | 2 | 1 | 0 |
| Metabolism and nutrition disorders | Hypoglycaemia | 2 | 1 | 0 |
| Metabolism and nutrition disorders | Hyponatraemia | 1 | 1 | 0 |
| Vascular disorders | Hypotension | 1 | 0 | 0 |
| Infections and infestations | Infection | 1 | 1 | 0 |
| Infections and infestations | Influenza | 1 | 1 | 0 |
| Metabolism and nutrition disorders | Lactic acidosis | 1 | 1 | 0 |
| Hepatobiliary disorders | Liver disorder | 1 | 1 | 0 |
| Investigations | Liver function test abnormal | 1 | 1 | 0 |

| MedDRA system organ class ⁱ | MedDRA reaction term ⁱⁱ | Number of cases ⁱⁱⁱ | Number of cases with a single suspected medicine ^{iv} | Number of cases where death was a reported outcome ^v |
|---|--------------------------------------|--------------------------------|--|---|
| Blood and lymphatic system disorders | Lymphopenia | 1 | 0 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | Neoplasm malignant | 1 | 1 | 0 |
| Renal and urinary disorders | Nephropathy | 1 | 0 | 0 |
| General disorders and administration site conditions | Oedema peripheral | 1 | 1 | 0 |
| Infections and infestations | Oral candidiasis | 1 | 1 | 0 |
| Gastrointestinal disorders | Oral pain | 1 | 1 | 0 |
| Infections and infestations | Orchitis | 1 | 1 | 0 |
| Metabolism and nutrition disorders | Fluid overload | 1 | 1 | 0 |
| Hepatobiliary disorders | Gallbladder disorder | 1 | 1 | 0 |
| Infections and infestations | Gastroenteritis | 1 | 1 | 0 |
| Investigations | Glycosylated haemoglobin increased | 1 | 1 | 0 |
| Investigations | Haematocrit increased | 1 | 1 | 0 |
| Gastrointestinal disorders | Diarrhoea | 1 | 1 | 0 |
| Metabolism and nutrition disorders | Hyperkalaemia | 1 | 1 | 0 |
| Skin and subcutaneous tissue disorders | Hyperkeratosis | 1 | 1 | 0 |
| Investigations | Haemoglobin increased | 1 | 1 | 0 |
| Investigations | Heart rate increased | 1 | 1 | 0 |
| Hepatobiliary disorders | Hepatic function abnormal | 1 | 1 | 0 |
| Metabolism and nutrition disorders | Hypercholesterolaemia | 1 | 1 | 0 |
| Investigations | Blood potassium increased | 1 | 1 | 0 |
| Investigations | Blood pressure decreased | 1 | 1 | 0 |
| Cardiac disorders | Cardiac failure | 1 | 0 | 0 |
| Nervous system disorders | Cerebrovascular accident | 1 | 0 | 0 |
| General disorders and administration site conditions | Chest discomfort | 1 | 1 | 0 |
| General disorders and administration site conditions | Condition aggravated | 1 | 1 | 0 |
| Investigations | Creatinine renal clearance decreased | 1 | 1 | 0 |
| Cardiac disorders | Aortic valve incompetence | 1 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | Arthralgia | 1 | 1 | 0 |
| Metabolism and nutrition disorders | Acidosis hyperchloraemic | 1 | 0 | 0 |
| Nervous system disorders | Ageusia | 1 | 1 | 0 |

| MedDRA system organ class ⁱ | MedDRA reaction term ⁱⁱ | Number of cases ⁱⁱⁱ | Number of cases with a single suspected medicine ^{iv} | Number of cases where death was a reported outcome ^v |
|---|---|--------------------------------|--|---|
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | Bile duct cancer | 1 | 1 | 0 |
| Skin and subcutaneous tissue disorders | Blister | 1 | 1 | 0 |
| Psychiatric disorders | Delirium | 1 | 0 | 0 |
| Psychiatric disorders | Depression | 1 | 1 | 0 |
| Metabolism and nutrition disorders | Diabetes mellitus inadequate control | 1 | 0 | 0 |
| Gastrointestinal disorders | Dry mouth | 1 | 1 | 0 |
| Skin and subcutaneous tissue disorders | Dry skin | 1 | 1 | 0 |
| Nervous system disorders | Dysgeusia | 1 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | Dysphonia | 1 | 1 | 0 |
| Respiratory, thoracic and mediastinal disorders | Dyspnoea | 1 | 0 | 0 |
| Skin and subcutaneous tissue disorders | Eczema | 1 | 1 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | Lung neoplasm malignant | 1 | 1 | 0 |
| Investigations | Urine output increased | 1 | 1 | 0 |
| Cardiac disorders | Cardiac disorder | 1 | 1 | 0 |
| Reproductive system and breast disorders | Genital haemorrhage | 1 | 1 | 0 |
| Metabolism and nutrition disorders | Decreased appetite | 1 | 1 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | Renal neoplasm | 1 | 1 | 0 |
| General disorders and administration site conditions | Ill-defined disorder | 1 | 1 | 0 |
| General disorders and administration site conditions | Disease progression | 1 | 1 | 0 |
| Psychiatric disorders | Psychotic disorder | 1 | 0 | 0 |
| Infections and infestations | Cellulitis of male external genital organ | 1 | 1 | 0 |
| Hepatobiliary disorders | Liver injury | 1 | 0 | 0 |
| Reproductive system and breast disorders | Vulvovaginal burning sensation | 1 | 1 | 0 |
| Skin and subcutaneous tissue disorders | Skin plaque | 1 | 1 | 0 |
| Reproductive system and breast disorders | Vulvovaginal pain | 1 | 1 | 0 |
| Investigations | Weight increased | 1 | 1 | 0 |

| MedDRA system organ class ⁱ | MedDRA reaction term ⁱⁱ | Number of cases ⁱⁱⁱ | Number of cases with a single suspected medicine ^{iv} | Number of cases where death was a reported outcome ^v |
|--|-------------------------------------|--------------------------------|--|---|
| Musculoskeletal and connective tissue disorders | Spinal pain | 1 | 1 | 0 |
| Nervous system disorders | Visual field defect | 1 | 0 | 0 |
| Infections and infestations | Urinary tract infection bacterial | 1 | 1 | 0 |
| Reproductive system and breast disorders | Vulvovaginal pruritus | 1 | 1 | 0 |
| Gastrointestinal disorders | Gastric disorder | 1 | 1 | 0 |
| Vascular disorders | Aortic dilatation | 1 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | Lupus-like syndrome | 1 | 0 | 0 |
| Infections and infestations | Candiduria | 1 | 1 | 0 |
| Vascular disorders | Deep vein thrombosis | 1 | 1 | 0 |
| Infections and infestations | Pulmonary sepsis | 1 | 1 | 0 |
| Gastrointestinal disorders | Oesophageal rupture | 1 | 1 | 0 |
| Infections and infestations | Escherichia urinary tract infection | 1 | 1 | 0 |
| Reproductive system and breast disorders | Penile blister | 1 | 0 | 0 |
| Blood and lymphatic system disorders | Pancytopenia | 1 | 1 | 0 |
| Investigations | Platelet count decreased | 1 | 1 | 0 |
| Infections and infestations | Pneumonia | 1 | 1 | 0 |
| Metabolism and nutrition disorders | Metabolic acidosis | 1 | 0 | 0 |
| Cardiac disorders | Mitral valve incompetence | 1 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | Muscle atrophy | 1 | 0 | 0 |
| General disorders and administration site conditions | Pyrexia | 1 | 0 | 0 |
| Metabolism and nutrition disorders | Polydipsia | 1 | 0 | 0 |
| Renal and urinary disorders | Polyuria | 1 | 0 | 0 |
| Renal and urinary disorders | Proteinuria | 1 | 1 | 0 |
| Respiratory, thoracic and mediastinal disorders | Pulmonary embolism | 1 | 1 | 0 |
| Cardiac disorders | Tachycardia | 1 | 0 | 0 |
| General disorders and administration site conditions | Thirst | 1 | 1 | 0 |
| Infections and infestations | Tinea cruris | 1 | 1 | 0 |
| Cardiac disorders | Tricuspid valve incompetence | 1 | 0 | 0 |
| Renal and urinary disorders | Urinary incontinence | 1 | 0 | 0 |
| Renal and urinary disorders | Urinary retention | 1 | 1 | 0 |

| MedDRA system organ class ⁱ | MedDRA reaction term ⁱⁱ | Number of cases ⁱⁱⁱ | Number of cases with a single suspected medicine ^{iv} | Number of cases where death was a reported outcome ^v |
|--|-------------------------------------|--------------------------------|--|---|
| Nervous system disorders | Somnolence | 1 | 1 | 0 |
| Skin and subcutaneous tissue disorders | Stevens-Johnson syndrome | 1 | 1 | 0 |
| Skin and subcutaneous tissue disorders | Rash generalised | 1 | 1 | 0 |
| Skin and subcutaneous tissue disorders | Rash maculo-papular | 1 | 1 | 0 |
| Infections and infestations | Rash pustular | 1 | 1 | 0 |
| Infections and infestations | Renal abscess | 1 | 1 | 0 |
| Renal and urinary disorders | Renal disorder | 1 | 1 | 0 |
| Eye disorders | Retinal disorder | 1 | 0 | 0 |
| Eye disorders | Retinopathy | 1 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | Rhabdomyolysis | 1 | 0 | 0 |
| Nervous system disorders | Seizure | 1 | 1 | 0 |
| Renal and urinary disorders | Renal tubular injury | 1 | 0 | 0 |
| Reproductive system and breast disorders | Penile burning sensation | 1 | 1 | 0 |
| Injury, poisoning and procedural complications | Intentional product misuse | 1 | 1 | 0 |
| General disorders and administration site conditions | Multiple organ dysfunction syndrome | 1 | 1 | 1 |
| Renal and urinary disorders | End stage renal disease | 1 | 1 | 0 |
| Gastrointestinal disorders | Anal incontinence | 1 | 0 | 0 |

Footnotes

ⁱ A description of what, in general terms, was affected by the adverse event, as described by the Medical Dictionary for Regulatory Activities MedDRA (for example 'cardiac disorders')

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ⁱⁱⁱ The number of cases for which each type of adverse event was reported

^{iv} Results show where a medicine is the only medicine suspected to be related to the adverse event

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Database of Adverse Event Notifications - medicines

Medicine summary

You searched for the following **6 medicines** between **01/01/2000 – 18/10/2017**:

- JARDIAMET 12.5 mg / 500 mg (Empagliflozin-Metformin Hydrochloride)
- Jardiamet 12.5 mg/1000 mg (Empagliflozin-Metformin Hydrochloride)
- Jardiamet NOS (Empagliflozin-Metformin Hydrochloride)
- Jardiance (Empagliflozin)
- Not specified (Empagliflozin)
- Not specified (Empagliflozin-Metformin Hydrochloride)

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(Multiple adverse events have been reported for some patients)

Number of cases with a single suspected medicine: 117

(The TGA thinks there is a possibility that the medicine caused the adverse event)

Number of cases where death was a reported outcome: 0

(These reports of death may or may not have been a result of taking a medicine)

| MedDRA system organ class ⁱ | MedDRA reaction term ⁱⁱ | Number of cases ⁱⁱⁱ | Number of cases with a single suspected medicine ^{iv} | Number of cases where death was a reported outcome ^v |
|--|--------------------------------------|--------------------------------|--|---|
| Metabolism and nutrition disorders | Diabetic ketoacidosis | 60 | 52 | 0 |
| Gastrointestinal disorders | Vomiting | 13 | 12 | 0 |
| Metabolism and nutrition disorders | Ketoacidosis | 10 | 10 | 0 |
| Gastrointestinal disorders | Nausea | 9 | 6 | 0 |
| General disorders and administration site conditions | Malaise | 8 | 8 | 0 |
| Renal and urinary disorders | Acute kidney injury | 6 | 3 | 0 |
| Infections and infestations | Urinary tract infection | 5 | 3 | 0 |
| Injury, poisoning and procedural complications | Off label use | 5 | 4 | 0 |
| Metabolism and nutrition disorders | Polydipsia | 5 | 2 | 0 |
| Vascular disorders | Hypotension | 5 | 4 | 0 |
| Gastrointestinal disorders | Diarrhoea | 4 | 4 | 0 |
| Gastrointestinal disorders | Abdominal pain | 4 | 4 | 0 |
| Infections and infestations | Cellulitis | 4 | 4 | 0 |
| General disorders and administration site conditions | Pyrexia | 4 | 4 | 0 |
| Investigations | Weight decreased | 4 | 3 | 0 |
| Investigations | Blood ketone body increased | 3 | 3 | 0 |
| Skin and subcutaneous tissue disorders | Erythema | 3 | 3 | 0 |
| Investigations | Glomerular filtration rate decreased | 3 | 1 | 0 |
| Metabolism and nutrition disorders | Hyperglycaemia | 3 | 2 | 0 |
| Gastrointestinal disorders | Pancreatitis | 3 | 2 | 0 |
| Gastrointestinal disorders | Pancreatitis acute | 3 | 3 | 0 |
| Renal and urinary disorders | Nocturia | 2 | 2 | 0 |
| Cardiac disorders | Myocardial infarction | 2 | 2 | 0 |
| Metabolism and nutrition disorders | Metabolic acidosis | 2 | 1 | 0 |
| Nervous system disorders | Migraine | 2 | 1 | 0 |

| MedDRA system organ class ⁱ | MedDRA reaction term ⁱⁱ | Number of cases ⁱⁱⁱ | Number of cases with a single suspected medicine ^{iv} | Number of cases where death was a reported outcome ^v |
|--|---|--------------------------------|--|---|
| Musculoskeletal and connective tissue disorders | Muscle spasms | 2 | 2 | 0 |
| Metabolism and nutrition disorders | Hyperkalaemia | 2 | 1 | 0 |
| Metabolism and nutrition disorders | Hypoglycaemia | 2 | 2 | 0 |
| Metabolism and nutrition disorders | Hyponatraemia | 2 | 2 | 0 |
| Metabolism and nutrition disorders | Lactic acidosis | 2 | 1 | 0 |
| Nervous system disorders | Lethargy | 2 | 2 | 0 |
| Vascular disorders | Circulatory collapse | 2 | 1 | 0 |
| Nervous system disorders | Dizziness | 2 | 1 | 0 |
| Gastrointestinal disorders | Dry mouth | 2 | 1 | 0 |
| Respiratory, thoracic and mediastinal disorders | Dyspnoea | 2 | 2 | 0 |
| Musculoskeletal and connective tissue disorders | Back pain | 2 | 2 | 0 |
| Psychiatric disorders | Confusional state | 2 | 1 | 0 |
| Gastrointestinal disorders | Constipation | 2 | 2 | 0 |
| Respiratory, thoracic and mediastinal disorders | Cough | 2 | 2 | 0 |
| Metabolism and nutrition disorders | Dehydration | 2 | 2 | 0 |
| Investigations | Blood glucose increased | 2 | 2 | 0 |
| Renal and urinary disorders | Polyuria | 2 | 1 | 0 |
| Infections and infestations | Sepsis | 2 | 2 | 0 |
| Nervous system disorders | Somnolence | 2 | 1 | 0 |
| Nervous system disorders | Syncope | 2 | 2 | 0 |
| Cardiac disorders | Tachycardia | 2 | 2 | 0 |
| Renal and urinary disorders | Renal impairment | 2 | 2 | 0 |
| Infections and infestations | Respiratory tract infection | 1 | 1 | 0 |
| Metabolism and nutrition disorders | Hyperglycaemic hyperosmolar nonketotic syndrome | 1 | 1 | 0 |
| Reproductive system and breast disorders | Penile oedema | 1 | 1 | 0 |
| Infections and infestations | Oral herpes | 1 | 1 | 0 |
| Renal and urinary disorders | Lower urinary tract symptoms | 1 | 1 | 0 |
| Infections and infestations | Candida infection | 1 | 1 | 0 |
| General disorders and administration site conditions | Thirst | 1 | 1 | 0 |
| Nervous system disorders | Tremor | 1 | 1 | 0 |
| Renal and urinary disorders | Urinary incontinence | 1 | 1 | 0 |

| MedDRA system organ class ⁱ | MedDRA reaction term ⁱⁱ | Number of cases ⁱⁱⁱ | Number of cases with a single suspected medicine ^{iv} | Number of cases where death was a reported outcome ^v |
|--|------------------------------------|--------------------------------|--|---|
| Renal and urinary disorders | Urinary retention | 1 | 1 | 0 |
| Nervous system disorders | Post herpetic neuralgia | 1 | 1 | 0 |
| Reproductive system and breast disorders | Prostatitis | 1 | 1 | 0 |
| Skin and subcutaneous tissue disorders | Pruritus | 1 | 1 | 0 |
| Infections and infestations | Pyelonephritis acute | 1 | 1 | 0 |
| Infections and infestations | Pyuria | 1 | 1 | 0 |
| Skin and subcutaneous tissue disorders | Rash | 1 | 1 | 0 |
| Respiratory, thoracic and mediastinal disorders | Respiratory disorder | 1 | 1 | 0 |
| Eye disorders | Retinal vein occlusion | 1 | 1 | 0 |
| Eye disorders | Retinopathy | 1 | 0 | 0 |
| Investigations | Blood ketone body present | 1 | 1 | 0 |
| Nervous system disorders | Restless legs syndrome | 1 | 1 | 0 |
| Metabolism and nutrition disorders | Decreased appetite | 1 | 0 | 0 |
| General disorders and administration site conditions | Adverse drug reaction | 1 | 1 | 0 |
| Surgical and medical procedures | Gastrectomy | 1 | 1 | 0 |
| Gastrointestinal disorders | Gastric disorder | 1 | 1 | 0 |
| Ear and labyrinth disorders | Vertigo | 1 | 1 | 0 |
| Eye disorders | Vision blurred | 1 | 1 | 0 |
| Renal and urinary disorders | Tubulointerstitial nephritis | 1 | 1 | 0 |
| General disorders and administration site conditions | Concomitant disease progression | 1 | 1 | 0 |
| Nervous system disorders | Brain oedema | 1 | 1 | 0 |
| Renal and urinary disorders | Leukocyturia | 1 | 0 | 0 |
| Infections and infestations | Staphylococcal bacteraemia | 1 | 1 | 0 |
| Surgical and medical procedures | Diabetes mellitus management | 1 | 0 | 0 |
| Investigations | Blood luteinising hormone abnormal | 1 | 1 | 0 |
| Investigations | Blood pH abnormal | 1 | 1 | 0 |
| Investigations | Blood pressure decreased | 1 | 1 | 0 |
| Investigations | Blood pressure systolic decreased | 1 | 1 | 0 |
| Cardiac disorders | Cardiac arrest | 1 | 1 | 0 |
| Investigations | Cardiac output decreased | 1 | 1 | 0 |
| Gastrointestinal disorders | Abdominal pain upper | 1 | 1 | 0 |
| Infections and infestations | Abscess | 1 | 1 | 0 |

| MedDRA system organ class ⁱ | MedDRA reaction term ⁱⁱ | Number of cases ⁱⁱⁱ | Number of cases with a single suspected medicine ^{iv} | Number of cases where death was a reported outcome ^v |
|--|-------------------------------------|--------------------------------|--|---|
| Metabolism and nutrition disorders | Acidosis | 1 | 1 | 0 |
| Nervous system disorders | Altered state of consciousness | 1 | 1 | 0 |
| Psychiatric disorders | Anxiety | 1 | 1 | 0 |
| Surgical and medical procedures | Aortic valve replacement | 1 | 1 | 0 |
| Psychiatric disorders | Depression | 1 | 1 | 0 |
| Nervous system disorders | Diabetic coma | 1 | 1 | 0 |
| Nervous system disorders | Diabetic hyperosmolar coma | 1 | 1 | 0 |
| Investigations | Blood creatinine increased | 1 | 0 | 0 |
| Investigations | Blood glucose decreased | 1 | 1 | 0 |
| Nervous system disorders | Cerebrovascular accident | 1 | 1 | 0 |
| General disorders and administration site conditions | Chest pain | 1 | 0 | 0 |
| Renal and urinary disorders | Dysuria | 1 | 1 | 0 |
| Investigations | Electrocardiogram QT prolonged | 1 | 1 | 0 |
| Eye disorders | Dry eye | 1 | 1 | 0 |
| General disorders and administration site conditions | Condition aggravated | 1 | 1 | 0 |
| Metabolism and nutrition disorders | Gout | 1 | 1 | 0 |
| Nervous system disorders | Headache | 1 | 1 | 0 |
| Injury, poisoning and procedural complications | Fall | 1 | 1 | 0 |
| General disorders and administration site conditions | Fatigue | 1 | 1 | 0 |
| Investigations | Fibrin D dimer increased | 1 | 1 | 0 |
| Metabolism and nutrition disorders | Fluid retention | 1 | 1 | 0 |
| Vascular disorders | Flushing | 1 | 1 | 0 |
| Investigations | Glomerular filtration rate abnormal | 1 | 1 | 0 |
| Investigations | Liver function test abnormal | 1 | 1 | 0 |
| Infections and infestations | Lower respiratory tract infection | 1 | 1 | 0 |
| Nervous system disorders | Memory impairment | 1 | 0 | 0 |
| Surgical and medical procedures | Knee arthroplasty | 1 | 1 | 0 |
| Skin and subcutaneous tissue disorders | Hyperhidrosis | 1 | 0 | 0 |
| Metabolism and nutrition disorders | Hypovolaemia | 1 | 1 | 0 |
| Nervous system disorders | Incoherent | 1 | 0 | 0 |
| Infections and infestations | Influenza | 1 | 1 | 0 |
| Investigations | Insulin C-peptide decreased | 1 | 0 | 0 |

| MedDRA system organ class ⁱ | MedDRA reaction term ⁱⁱ | Number of cases ⁱⁱⁱ | Number of cases with a single suspected medicine ^{iv} | Number of cases where death was a reported outcome ^v |
|---|------------------------------------|--------------------------------|--|---|
| Musculoskeletal and connective tissue disorders | Myalgia | 1 | 1 | 0 |
| Gastrointestinal disorders | Mouth ulceration | 1 | 1 | 0 |
| Gastrointestinal disorders | Abdominal discomfort | 1 | 0 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | Neoplasm | 1 | 1 | 0 |
| General disorders and administration site conditions | Oedema peripheral | 1 | 1 | 0 |
| Injury, poisoning and procedural complications | Overdose | 1 | 0 | 0 |
| Cardiac disorders | Palpitations | 1 | 0 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | Pancreatic carcinoma | 1 | 1 | 0 |
| Infections and infestations | Parotitis | 1 | 1 | 0 |
| Vascular disorders | Peripheral ischaemia | 1 | 0 | 0 |
| Congenital, familial and genetic disorders | Phimosis | 1 | 1 | 0 |
| Infections and infestations | Pneumonia | 1 | 1 | 0 |
| Renal and urinary disorders | Pollakiuria | 1 | 1 | 0 |

Footnotes

ⁱ A description of what, in general terms, was affected by the adverse event, as described by the Medical Dictionary for Regulatory Activities MedDRA (for example 'cardiac disorders')

ⁱⁱ A description of the adverse event as defined by MedDRA; these adverse events are grouped by system organ class. You can use the MedlinePlus medical dictionary <<http://www.nlm.nih.gov/medlineplus/mplusdictionary.html>> to look up terms.

ⁱⁱⁱ The number of cases for which each type of adverse event was reported

^{iv} Results show where a medicine is the only medicine suspected to be related to the adverse event

^v These reports of death may or may not have been the result of taking a medicine