Report Run Date: 14-Jul-2021

Data Lock Date: 13-Jul-2021 18:30:06

Earliest Reaction Date: 01-Jan-2006 MedDRA Version: MedDRA 24.0

Opioids and UK Spontaneous ADR reports where opioid and benzodiazepines are reported as co-suspect

2019: medicines.

Reaction Name	Total	Fatal
Blood disorders		
Anaemias NEC		
Anaemia	1	0
Coagulopathies		
Coagulopathy	1	0
Neutropenias		
Neutropenia	3	0
Blood disorders SOC TOTAL	5	0

Reaction Name	Total	Fatal
Cardiac disorders		
Myocardial disorders NEC		
Ventricular hypokinesia	1	0
Rate and rhythm disorders NEC		
Arrhythmia	1	1
Bradycardia	1	0
Tachycardia	2	0
Cardiac disorders SOC TOTAL	5	1

Reaction Name	Total	Fatal
Endocrine disorders		
Thyroid disorders NEC		
Euthyroid sick syndrome	1	0
Thyroid hypofunction disorders		
Hypothyroidism	1	0
Endocrine disorders SOC TOTAL	2	0

Reaction Name	Total	Fatal
Eve disorders		
Visual impairment and blindness (excl colour blindness)		
Visual acuity reduced	1	0
Visual pathway disorders		
Optic neuropathy	1	0
Eve disorders SOC TOTAL	2	0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
Acute and chronic pancreatitis		
Pancreatitis acute	1	0
Gastrointestinal disorders NEC		
Abdominal compartment syndrome	1	0
Gastric disorder	1	0
Gastrointestinal stenosis and obstruction NEC		
lleus	1	0
Malabsorption syndromes		
Malabsorption	1	0
Non-site specific gastrointestinal haemorrhages		
Haematemesis	3	0
Oral soft tissue signs and symptoms		
Hypoaesthesia oral	1	0
Gastrointestinal disorders SOC TOTAL	9	0

Reaction Name	Total	Fatal
General disorders		
Febrile disorders		
Pyrexia	•	1 0
General signs and symptoms NEC		
Multiple organ dysfunction syndrome	•	1 0
Interactions		
Alcohol interaction		2 0
Drug interaction	-	7 0
Pain and discomfort NEC		
Pain	•	1 0
Therapeutic and nontherapeutic responses		
Drug ineffective	•	1 0
Inadequate analgesia	,	1 0
General disorders SOC TOTAL	14	4l 0

Reaction Name	Total	Fatal
Hepatic disorders		
Hepatic failure and associated disorders		
Hepatic failure	2	1
Hepatocellular damage and hepatitis NEC		
Liver injury	1	0
Hepatic disorders SOC TOTAL	3	1

Name: Opioids and Benzodiazepines 2019

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Reaction Name	Total	Fatal
Immune system disorders		
Allergies to foods, food additives, drugs and other chemicals		
Drug hypersensitivity	1	0
Immune system disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Infections		
Fungal infections NEC		
Fungal infection	1	0
Infections NEC		
Infection	3	0
Lower respiratory tract and lung infections		
Pneumonia	2	1
Sepsis, bacteraemia, viraemia and fungaemia NEC		
Sepsis	1	1
Infections SOC TOTAL	7	2

Reaction Name	Total	Fatal
Injuries		
Intentional product misuses		
Intentional product misuse	2	0
Medication errors, product use errors and issues NEC		
Product use in unapproved indication	1	0
Non-site specific injuries NEC		
Fall	1	0
Overdoses NEC		
Overdose	6	5
Poisoning and toxicity		
Toxicity to various agents	11	6
Product administration errors and issues		
Accidental overdose	1	1
Incorrect dose administered	1	0
Product monitoring errors and issues		
Labelled drug-drug interaction medication error	1	0
Renal and urinary tract injuries NEC		
Haematuria traumatic	1	0
Injuries SOC TOTAL	25	12

Reaction Name	Total	Fatal
Investigations		
Heart rate and pulse investigations		
Pulse absent	1	0
Liver function analyses		
Liver function test abnormal	2	0
Neurologic diagnostic procedures		
Coma scale abnormal	1	0
Physical examination procedures and organ system status		
Weight decreased	1	0
Investigations SOC TOTAL	5	0

Reaction Name	Total	Fatal
Metabolic disorders		
Calcium metabolism disorders		
Hypercalcaemia	1	0
Hyperglycaemic conditions NEC		
Hyperglycaemia	1	0
Hypoglycaemic conditions NEC		
Hypoglycaemia	2	2 0
Mixed acid-base disorders		
Acidosis	1	0
Potassium imbalance		
Hyperkalaemia	1	0
Hypokalaemia	1	0
Sodium imbalance		
Hypernatraemia	2	0
Metabolic disorders SOC TOTAL	ę	el o

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Musculoskeletal and connective tissue conditions NEC		
Muscle contracture	1	0
Muscle & tissue disorders SOC TOTAL	1	l o

Earliest Reaction Date. 01-Jan-2000 MedDRA Version. MedDRA 24.0		
Reaction Name	<u> Total</u>	<u>Fatal</u>
Nervous system disorders		
Acute polyneuropathies		
Intensive care unit acquired weakness	2	0
Central nervous system haemorrhages and cerebrovascular accidents		
Cerebrovascular accident	1	1
Coma states		
Coma	1	0
Cortical dysfunction NEC		
Aphasia	1	0
Disturbances in consciousness NEC		
Somnolence	3	0
Memory loss (excl dementia)		
Amnesia	2	0
Memory impairment	2	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	2	0
Mental impairment	1	0
Narcolepsy and hypersomnia		
Hypersomnia	1	0
Neurological signs and symptoms NEC		
Unresponsive to stimuli	2	0
Seizures and seizure disorders NEC		
Partial seizures	2	0
Seizure	1	0
Status epilepticus	1	0
Nervous system disorders SOC TOTAL	22	1

Reaction Name	Total	Fatal
Psychiatric disorders		
Abnormal behaviour NEC		
Abnormal behaviour	2	0
Behaviour disorder	1	0
Confusion and disorientation		
Confusional state	1	0
Deliria		
Intensive care unit delirium	1	0
Disturbances in initiating and maintaining sleep		
Insomnia	1	0
Emotional and mood disturbances NEC		
Mood altered	1	0
Psychotic disorder NEC		
Psychotic disorder	1	0
Substance related and addictive disorders		
Drug abuse	2	0
Drug dependence	2	0
Suicidal and self-injurious behaviour		
Completed suicide	1	1
Psychiatric disorders SOC TOTAL	13	1

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Reaction Name	Total	Fatal
Renal & urinary disorders		
Bladder and urethral symptoms		
Urinary retention	1	0
Renal failure and impairment		
Acute kidney injury	2	0
Renal failure	2	1
Renal & urinary disorders SOC TOTAL	5	1

Reaction Name	Total	Fatal
Respiratory disorders		
Breathing abnormalities		
Apnoea	1	0
Respiratory depression	1	1
Pulmonary oedemas		
Acute lung injury	1	0
Respiratory failures (excl neonatal)		
Respiratory failure	1	0
Respiratory disorders SOC TOTAL	4	1

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Reaction Name	Total	Fatal
Skin disorders		
Rashes, eruptions and exanthems NEC		
Rash	1	0
Rash erythematous	1	0
Skin injuries and mechanical dermatoses		
Decubitus ulcer	1	0
Skin disorders SOC TOTAL	3	0

Reaction Name	Total	Fatal
Vascular disorders		
Blood pressure disorders NEC		
Labile blood pressure	2	0
Non-site specific vascular disorders NEC		
Haemodynamic instability	1	0
Peripheral embolism and thrombosis		
Deep vein thrombosis	1	0
Pelvic venous thrombosis	1	0
Thrombophlebitis	1	0
Vascular hypotensive disorders		
Hypotension	2	0
Vascular disorders SOC TOTAL	8	0
TOTAL REACTIONS FOR DRUG	143	20
TOTAL REPORTS	39	
TOTAL FATAL OUTCOME REPORTS		20