

Case Series Drug Analysis Print

Name: Opioids and Benzodiazepines 2021

Report Run Date: 14-Jul-2021

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

Earliest Reaction Date: 15-Apr-2002

MedDRA Version: MedDRA 24.0

Opioids and Benzodiazepines 2021: UK Spontaneous ADR reports where opioid and benzodiazepines are reported as co-suspect medicines.

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Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias NEC</i>		
Anaemia	4	0
<i>Coagulopathies</i>		
Coagulopathy	7	0
Blood disorders SOC TOTAL	11	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Coronary artery disorders NEC</i>		
Coronary artery disease	1	0
<i>Ischaemic coronary artery disorders</i>		
Myocardial ischaemia	1	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	2	0
Tachycardia	11	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	2	0
Cardiac disorders SOC TOTAL	17	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Inner ear signs and symptoms</i>		
Tinnitus	7	0
Ear disorders SOC TOTAL	7	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Thyroid disorders NEC</i>		
Euthyroid sick syndrome	1	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	4	0
Endocrine disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Ocular disorders NEC</i>		
Eye pain	7	0
<i>Pupil disorders</i>		
Mydriasis	7	0
<i>Visual disorders NEC</i>		
Vision blurred	7	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Visual impairment	8	0
Eye disorders SOC TOTAL	29	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal wall conditions NEC</i>		
Abdominal wall haematoma	2	0
<i>Colitis (excl infective)</i>		
Colitis ischaemic	2	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	7	0
<i>Duodenal ulcers and perforation</i>		
Duodenal ulcer	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain upper	1	0
Abdominal rigidity	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	2	0
<i>Gastrointestinal disorders NEC</i>		
Abdominal compartment syndrome	2	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Ileus	2	0
<i>Gastrointestinal vascular occlusion and infarction</i>		
Intestinal ischaemia	1	0
<i>Malabsorption syndromes</i>		
Malabsorption	4	0
<i>Nausea and vomiting symptoms</i>		
Retching	1	0
Vomiting	6	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	3	0
Haematemesis	3	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	7	0
<i>Tongue signs and symptoms</i>		
Swollen tongue	7	0
Gastrointestinal disorders SOC TOTAL	52	0

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General disorders		
<i>Asthenic conditions</i>		
Asthenia	6	0
Fatigue	7	0
<i>Death and sudden death</i>		
Death	1	0
<i>Febrile disorders</i>		
Pyrexia	10	0
<i>Feelings and sensations NEC</i>		
Feeling jittery	6	0
Feeling of body temperature change	7	0
<i>Gait disturbances</i>		
Gait disturbance	7	0
<i>General signs and symptoms NEC</i>		
Disease recurrence	1	0
Illness	6	0
Multiple organ dysfunction syndrome	4	3
Swelling face	7	0
<i>Interactions</i>		
Alcohol interaction	4	0
Drug interaction	14	0
Potentiating drug interaction	1	0
<i>Pain and discomfort NEC</i>		
Chest pain	1	0
Pain	1	0
<i>Therapeutic and nontherapeutic responses</i>		
Drug ineffective	5	1
Drug tolerance	1	0
Therapeutic product effect incomplete	1	0
Therapeutic product ineffective	4	0
<i>Ulcers NEC</i>		
Ulcer	2	0
<i>Withdrawal and rebound effects</i>		
Drug withdrawal syndrome	9	0
Withdrawal syndrome	2	0
General disorders SOC TOTAL	107	4

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Hepatic failure and associated disorders</i>		
Acute hepatic failure	1	0
Hepatic failure	2	0
Hepatorenal syndrome	2	0
<i>Hepatic vascular disorders</i>		
Hepatic ischaemia	2	1
<i>Hepatocellular damage and hepatitis NEC</i>		
Hepatitis fulminant	2	0
Hepatocellular injury	2	0
Liver injury	2	0
Hepatic disorders SOC TOTAL	13	1

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Drug hypersensitivity	3	0
Immune system disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Diverticulitis	1	0
<i>Clostridia infections</i>		
Pseudomembranous colitis	2	0
<i>Fungal infections NEC</i>		
Fungal infection	4	0
<i>Infections NEC</i>		
Infection	11	0
<i>Influenza viral infections</i>		
H1N1 influenza	6	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	3	1
Infections SOC TOTAL	27	1

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Reaction Name	Total	Fatal
Injuries		
<i>Anaesthetic and allied procedural complications</i>		
Unwanted awareness during anaesthesia	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	5	0
Maternal exposure during delivery	1	0
Maternal exposure during pregnancy	1	0
<i>Intentional product misuses</i>		
Intentional product misuse	4	0
<i>Intentional product use issues</i>		
Intentional product use issue	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	1	0
Product use in unapproved indication	11	0
<i>Non-site specific procedural complications</i>		
Post procedural haemorrhage	1	0
<i>Off label uses</i>		
Off label use	7	0
<i>Overdoses NEC</i>		
Overdose	5	1
<i>Poisoning and toxicity</i>		
Toxicity to various agents	54	43
<i>Renal and urinary tract injuries NEC</i>		
Haematuria traumatic	2	0
<i>Site specific injuries NEC</i>		
Limb injury	5	0
<i>Skin injuries NEC</i>		
Contusion	6	0
Injuries SOC TOTAL	105	44

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Reaction Name	Total	Fatal
Investigations		
<i>Gastrointestinal function diagnostic procedures</i>		
Gastric pH decreased	7	0
<i>Heart rate and pulse investigations</i>		
Heart rate increased	6	0
<i>Liver function analyses</i>		
Liver function test abnormal	5	0
<i>Mineral and electrolyte analyses</i>		
Blood sodium decreased	6	0
<i>Physical examination procedures and organ system status</i>		
Weight decreased	4	0
Investigations SOC TOTAL	28	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	6	0
<i>Calcium metabolism disorders</i>		
Hypercalcaemia	2	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	2	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	1	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Metabolic acidosis	2	0
<i>Potassium imbalance</i>		
Hyperkalaemia	2	0
<i>Sodium imbalance</i>		
Hypernatraemia	4	0
<i>Total fluid volume decreased</i>		
Hypovolaemia	2	0
Metabolic disorders SOC TOTAL	21	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Joint related signs and symptoms</i>		
Arthralgia	7	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle disorder	7	0
Muscle spasms	7	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	7	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Muscle contracture	4	0
Musculoskeletal stiffness	7	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	1	0
Muscle & tissue disorders SOC TOTAL	40	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Acute polyneuropathies</i>		
Intensive care unit acquired weakness	8	0
<i>Autonomic nervous system disorders</i>		
Autonomic nervous system imbalance	4	0
<i>Coordination and balance disturbances</i>		
Balance disorder	6	0
<i>Cortical dysfunction NEC</i>		
Aphasia	7	0
<i>Disturbances in consciousness NEC</i>		
Somnolence	7	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	7	0
Hypokinesia	1	0
<i>Dystonias</i>		
Dystonia	7	0
<i>Headaches NEC</i>		
Headache	8	0
<i>Memory loss (excl dementia)</i>		
Memory impairment	2	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	2	0
Disturbance in attention	6	0
<i>Muscle tone abnormal</i>		
Neuroleptic malignant syndrome	7	0
Serotonin syndrome	7	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	8	0
Drooling	7	0
<i>Neuromuscular disorders NEC</i>		
Neuromyopathy	1	0
<i>Olfactory nerve disorders</i>		
Parosmia	7	0
<i>Paraesthesias and dysaesthesias</i>		
Hypoaesthesia	7	0
Paraesthesia	7	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Paralysis	7	0
<i>Parkinson's disease and parkinsonism</i>		
Cogwheel rigidity	7	0
<i>Seizures and seizure disorders NEC</i>		
Partial seizures	2	0
Seizure	6	0
Status epilepticus	1	0
<i>Sensory abnormalities NEC</i>		
Restless legs syndrome	6	0
Sensory loss	6	0
<i>Speech and language abnormalities</i>		
Speech disorder	7	0
<i>Tremor (excl congenital)</i>		
Tremor	6	0
Nervous system disorders SOC TOTAL	164	0

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Labour onset and length abnormalities</i>		
Premature labour	6	0
Pregnancy conditions SOC TOTAL	6	0

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Reaction Name	Total	Fatal
<i>Product physical issues</i>		
Product physical issue	1	0
Product taste abnormal	1	0
null SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Behaviour disorder	2	0
<i>Anxiety symptoms</i>		
Agitation	7	0
Anxiety	6	0
<i>Confusion and disorientation</i>		
Confusional state	6	0
Disorientation	7	0
<i>Deliria</i>		
Delirium	9	0
Intensive care unit delirium	1	0
<i>Depressive disorders</i>		
Depression	6	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	6	0
Dissociation	6	0
<i>Emotional and mood disturbances NEC</i>		
Emotional disorder	6	0
Emotional distress	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	6	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucinations, mixed	7	0
<i>Increased physical activity levels</i>		
Restlessness	6	0
<i>Mood alterations with depressive symptoms</i>		
Feeling of despair	6	0
<i>Mood alterations with manic symptoms</i>		
Mania	6	0
<i>Parasomnias</i>		
Nightmare	6	0
<i>Perception disturbances NEC</i>		
Derealisation	6	0
<i>Psychotic disorder NEC</i>		
Psychotic disorder	7	0
<i>Schizophrenia NEC</i>		
Schizophrenia	7	0
<i>Sleep disorders NEC</i>		
Sleep disorder	6	0
<i>Substance related and addictive disorders</i>		
Drug abuse	11	1
Drug dependence	1	0
<i>Suicidal and self-injurious behaviour</i>		
Suicidal ideation	6	0
Psychiatric disorders SOC TOTAL	144	1

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Incontinence	6	0
Urinary retention	7	0
<i>Renal failure and impairment</i>		
Acute kidney injury	6	1
Renal failure	3	0
Renal impairment	2	0
<i>Urinary abnormalities</i>		
Haematuria	2	0
Renal & urinary disorders SOC TOTAL	26	1

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Menstruation and uterine bleeding NEC</i>		
Menstrual disorder	6	0
Reproductive & breast disorders SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	2	0
Dyspnoea	6	0
<i>Pulmonary oedemas</i>		
Acute lung injury	2	0
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	1	0
Respiratory disorders SOC TOTAL	11	0

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Reaction Name	Total	Fatal
Skin disorders		
<i>Apocrine and eccrine gland disorders</i>		
Hyperhidrosis	6	0
<i>Bullous conditions</i>		
Toxic epidermal necrolysis	1	0
<i>Dermal and epidermal conditions NEC</i>		
Skin discolouration	7	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	1	0
<i>Pruritus NEC</i>		
Pruritus	8	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	3	0
<i>Skin injuries and mechanical dermatoses</i>		
Decubitus ulcer	4	0
Skin disorders SOC TOTAL	30	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Psychiatric therapies</i>		
Psychiatric disorder prophylaxis	1	0
Surgical & medical procedures SOC TOTAL	1	0

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Vascular disorders		
<i>Blood pressure disorders NEC</i>		
Labile blood pressure	3	0
<i>Haemorrhages NEC</i>		
Haemorrhage	1	1
<i>Non-site specific vascular disorders NEC</i>		
Haemodynamic instability	2	0
<i>Peripheral embolism and thrombosis</i>		
Deep vein thrombosis	6	0
Pelvic venous thrombosis	1	0
Thrombophlebitis	4	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	7	0
<i>Site specific vascular disorders NEC</i>		
Pallor	6	0
<i>Vascular hypotensive disorders</i>		
Hypotension	2	0
Vascular disorders SOC TOTAL	32	1
TOTAL REACTIONS FOR DRUG	887	53
TOTAL REPORTS	85	
TOTAL FATAL OUTCOME REPORTS		53