#### Case Series Drug Analysis Print Name: Opioids and Benzodiazepines 2020

Report Run Date:14-Jul-2021Data Lock Date:13-Jul-2021 18:30:06Earliest Reaction Date:29-Aug-2019MedDRA Version:MedDRA 24.0

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

# Name: Opioids and Benzodiazepines 2020

 Report Run Date: 14-Jul-2021
 Data Lock Date: 13-Jul-2021 18:30:06

 Earliest Reaction Date: 29-Aug-2019
 MedDRA Version: MedDRA 24.0

 Total Fatal

Reaction Name	IOTAI	Fatal
Blood disorders		
Anaemias NEC		
Anaemia	2	0
Blood disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Cardiac disorders		
Heart failures NEC		
Cardiac failure	1	0
Myocardial disorders NEC		
Ventricular hypokinesia	1	0
Supraventricular arrhythmias		
Atrial fibrillation	1	0
Cardiac disorders SOC TOTAL	3	0

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Reaction Name		Total	Fatal
Congenital disorders			
Pulmonary and bronchial disorders conge	enital		
Cystic fibrosis		1	1
Congenital disorders SOC TOTAL		1	1

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

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<u> </u>	Fatal
1	0
1	0
1	0
3	0
	Total 1 1 1 3

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Flatulence, bloating and distension		
Abdominal distension	1	0
Gastrointestinal atonic and hypomotility disorders NEC		
Constipation	1	0
Malabsorption syndromes		
Malabsorption	1	C
Gastrointestinal disorders SOC TOTAL	3	

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Reaction Name	Total	Fatal
General disorders		
Death and sudden death		
Death	3	3
General signs and symptoms NEC		
Energy increased	1	0
Pain and discomfort NEC		
Pain	2	0
General disorders SOC TOTAL	6	3

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<u>Total</u>	Fatal
1	0
1	0
2	0
	1

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Reaction Name		Total	Fatal
Immune system disorders			
Anaphylactic and anaphylactoid responses			
Anaphylactic reaction		2	0
Immune system disorders SOC TOTAL		2	0

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Reaction Name	Tota		Fatal
Infections			<u>i atu</u>
Ear infections			
Ear infection		1	0
Fungal infections NEC			
Fungal infection		2	0
Infections NEC			
Infection		5	0
Localised infection		1	0
Lower respiratory tract and lung infections			
Infective pulmonary exacerbation of cystic	fibrosis	1	0
Infections SOC TOTAL		0	0

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Reaction Name	Total	Fatal
Injuries		
Intentional product use issues		
Intentional product use issue	1	0
Medication errors, product use errors and issues NEC		
Product use in unapproved indication	4	0
Non-site specific injuries NEC		
Fall	2	0
Off label uses		
Off label use	1	0
Overdoses NEC		
Intentional overdose	1	0
Overdose	10	0
Poisoning and toxicity		
Accidental poisoning	1	0
Toxicity to various agents	16	12
Product administration errors and issues		
Accidental overdose	1	0
Extra dose administered	1	0
Renal and urinary tract injuries NEC		
Haematuria traumatic	2	0
Injuries SOC TOTAL	40	12

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Reaction Name	Total	Fatal
Investigations		
Liver function analyses		
Liver function test abnormal	3	0
Physical examination procedures and organ system status		
Weight decreased	2	0
Investigations SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Metabolic disorders		
Hyperglycaemic conditions NEC		
Hyperglycaemia		1 0
Hypoglycaemic conditions NEC		
Hypoglycaemia		1 0
Potassium imbalance		
Hyperkalaemia		1 0
Hypokalaemia		1 0
Sodium imbalance		
Hypernatraemia		1 0
Metabolic disorders SOC TOTAL		5 0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle related signs and symptoms NEC		
Muscle atrophy	1	0
Musculoskeletal and connective tissue conditions NEC		
Muscle contracture	2	0
Musculoskeletal and connective tissue pain and discomfort		
Pain in extremity	1	0
Spondyloarthropathies		
Ankylosing spondylitis	1	0
Muscle & tissue disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Acute polyneuropathies		
Intensive care unit acquired weakness	4	0
Autonomic nervous system disorders		
Autonomic nervous system imbalance	1	0
Coma states		
Coma	6	0
Disturbances in consciousness NEC		
Loss of consciousness	1	0
Somnolence	2	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	3	0
Mononeuropathies		
Femoral nerve palsy	1	0
Neurological signs and symptoms NEC		
Unresponsive to stimuli	1	0
Peripheral neuropathies NEC		
Neuropathy peripheral	2	0
Sensory abnormalities NEC		
Allodynia	1	0
Nervous system disorders SOC TOTAL	22	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
Anxiety symptoms		
Anxiety	1	0
Deliria		
Delirium	1	0
Depressive disorders		
Depression	1	0
Disturbances in initiating and maintaining sleep		
Insomnia	1	0
Emotional and mood disturbances NEC		
Euphoric mood	1	0
Hallucinations (excl sleep-related)		
Hallucination	1	0
Mood alterations with depressive symptoms		
Depressed mood	1	0
Parasomnias		
Nightmare	1	0
Substance related and addictive disorders		
Drug abuse	9	0
Drug dependence	1	0
Suicidal and self-injurious behaviour		
Completed suicide	1	1
Suicidal ideation	1	0
Psychiatric disorders SOC TOTAL	20	1

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Reaction Name		Total	Fatal
Renal & urinary disorders			
Renal failure and impairment			
Acute kidney injury		1	0
Renal failure		1	1
Renal & urinary disorders SOC TOTAL		2	1

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Reaction Name	Total	<u>Fatal</u>
Skin disorders		
Bullous conditions		
Toxic epidermal necrolysis	1	0
Skin and subcutaneous tissue ulcerations		
Skin ulcer	1	0
Skin disorders SOC TOTAL	2	0

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Reaction Name	Total	<u>Fatal</u>
Vascular disorders		
Circulatory collapse and shock		
Circulatory collapse	2	2 0
Non-site specific vascular disorders NEC		
Haemodynamic instability	1	0
Peripheral embolism and thrombosis		
Deep vein thrombosis	3	0
Thrombophlebitis	2	0
Vascular disorders SOC TOTAL	8	0
TOTAL REACTIONS FOR DRUG	142	18
TOTAL REPORTS	39	
TOTAL FATAL OUTCOME REPORTS		18