Case Series Drug Analysis Print Name: Copy of Pollinex allergan immunotherapies

Report Run Date: 21-Jun-2023

Data Lock Date: 06-Jun-2023 18:30:03

Earliest Reaction Date: 20-Feb-1974 MedDRA Version: MedDRA 26.0

Copy of Pollinex

All UK spontaneous Pollinex reports received up to and including 06/06/2023

allergan

immunotherapies:

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Reaction Name	Total	Fatal
Blood disorders		
Lymphatic system disorders NEC		
Lymphadenopathy	2	0
Marrow depression and hypoplastic anaemias		
Aplastic anaemia	1	1
Blood disorders SOC TOTAL	3	1

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Reaction Name	Total	Fatal
Cardiac disorders		
Rate and rhythm disorders NEC		
Bradycardia	3	3 0
Tachycardia	2	0
Ventricular arrhythmias and cardiac arrest		
Cardiac arrest	1	ı o
Cardiac disorders SOC TOTAL		6 0

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Reaction Name	Total	Fatal
Eye disorders		
Ocular disorders NEC		
Periorbital oedema	1	0
Ocular nerve and muscle disorders		
Eye movement disorder	1	0
Ophthalmoplegia	2	0
Visual disorders NEC		
Diplopia	2	0
Visual field disorders		
Visual field defect	1	0
Visual impairment and blindness (excl colour blindness)		
Visual impairment	1	0
Eye disorders SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Diarrhoea (excl infective)		
Diarrhoea	2	0
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal pain	2	0
Abdominal pain upper	1	0
Gastrointestinal atonic and hypomotility disorders NEC		
Constipation	1	0
Gastrointestinal spastic and hypermotility disorders		
Defaecation urgency	1	0
Nausea and vomiting symptoms		
Nausea	4	0
Vomiting	2	0
Oral soft tissue signs and symptoms		
Paraesthesia oral	2	0
Gastrointestinal disorders SOC TOTAL	15	0

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Reaction Name	Total	Fatal
General disorders		
Asthenic conditions		
Asthenia	1	0
Fatigue	2	0
Malaise	10	0
Febrile disorders		
Pyrexia	2	0
Feelings and sensations NEC		
Chills	2	0
Feeling abnormal	1	0
Feeling hot	1	0
Sensation of foreign body	1	0
Gait disturbances		
Gait disturbance	3	0
General signs and symptoms NEC		
Swelling	1	0
Inflammations		
Granuloma	1	0
Injection site reactions		
Injection site atrophy	1	0
Injection site bruising	1	0
Injection site erythema	2	0
Injection site inflammation	1	0
Injection site mass	2	0
Injection site oedema	1	0
Injection site pruritus	9	0
Injection site reaction	9	0
Injection site swelling	4	0
Injection site urticaria	2	0
Oedema NEC		
Face oedema	1	0
Pain and discomfort NEC		
Chest discomfort	2	0
Chest pain	1	0
Therapeutic and nontherapeutic responses		
Adverse event	1	0
General disorders SOC TOTAL	55	0

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Reaction Name	Total	Fatal
Hepatic disorders		
Cholestasis and jaundice		
Jaundice	1	0
Hepatic disorders SOC TOTAL	1	l ol

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Reaction Name	Total	Fatal
Immune system disorders		
Allergic conditions NEC		
Hypersensitivity	1	0
Serum sickness-like reaction	1	0
Anaphylactic and anaphylactoid responses		
Anaphylactic reaction	23	2
Anaphylactoid reaction	6	0
Immune system disorders SOC TOTAL	31	2

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Reaction Name	Total	Fatal
Infections		
Eye and eyelid infections		
Conjunctivitis	1	0
Lower respiratory tract and lung infections		
Bronchitis	1	0
Pneumonia	2	0
Upper respiratory tract infections		
Rhinitis	2	0
Sinusitis	1	0
Infections SOC TOTAL	7	0

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Reaction Name	Total	Fatal
Injuries		
Skin injuries NEC		
Contusion	1	0
Injuries SOC TOTAL	1	l o

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Reaction Name	Total	Fatal
Investigations		
Blood gas and acid base analyses		
Oxygen saturation decreased	1	0
Carbohydrate tolerance analyses (incl diabetes)		
Blood glucose abnormal	1	0
Heart rate and pulse investigations		
Heart rate increased	1	0
Respiratory and pulmonary function diagnostic procedures		
Peak expiratory flow rate decreased	3	0
Vascular tests NEC (incl blood pressure)		
Blood pressure decreased	4	0
Investigations SOC TOTAL	10	0

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Reaction Name	Total	Fatal
Metabolic disorders		
Phosphorus metabolism disorders		
Hypophosphataemia	2	0
Metabolic disorders SOC TOTAL	2	ıl ol

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Arthropathies NEC		
Arthritis	1	0
Arthropathy	1	0
Polyarthritis	1	0
Connective tissue disorders NEC		
Polymyalgia rheumatica	1	0
Muscle weakness conditions		
Muscular weakness	1	0
Rheumatoid arthropathies		
Rheumatoid arthritis	1	0
Synovial disorders		
Synovitis	1	0
Tendon disorders		
Tendonitis	1	0
Muscle & tissue disorders SOC TOTAL	8	<u> </u>

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Reaction Name	Total	Fatal
Nervous system disorders		
Acute polyneuropathies		
Guillain-Barre syndrome	2	0
Disturbances in consciousness NEC		
Lethargy	3	0
Headaches NEC		
Headache	1	0
Mental impairment (excl dementia and memory loss)		
Disturbance in attention	1	0
Neurological signs and symptoms NEC		
Dizziness	9	0
Seizures and seizure disorders NEC		
Seizure	1	0
Nervous system disorders SOC TOTAL	17	0

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Reaction Name	<u>Total</u>	Fatal
Device malfunction events NEC		
Device occlusion	1	0
null SOC TOTAL	1	ıl ol

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Reaction Name	Total	Fatal
Psychiatric disorders		
Anxiety symptoms		
Agitation	2	0
Confusion and disorientation		
Confusional state	1	0
Psychiatric disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
Bladder and urethral symptoms		
Dysuria	1	0
Renal & urinary disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Respiratory disorders		
Breathing abnormalities		
Apnoeic attack	1	0
Dyspnoea	6	0
Respiratory depression	1	0
Bronchospasm and obstruction		
Asthma	6	0
Bronchospasm	3	3 0
Wheezing	7	7 0
Coughing and associated symptoms		
Cough	3	0
Laryngeal spasm, oedema and obstruction		
Laryngeal oedema	1	0
Respiratory failures (excl neonatal)		
Acute respiratory failure	1	0
Upper respiratory tract signs and symptoms		
Dysphonia	1	0
Respiratory disorders SOC TOTAL	30	ol o

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Reaction Name	Total	Fatal
Skin disorders		
Angioedemas		
Angioedema	2	0
Apocrine and eccrine gland disorders		
Cold sweat	1	0
Hyperhidrosis	2	0
Dermal and epidermal conditions NEC		
Skin discolouration	1	0
Skin lesion	1	0
Dermatitis and eczema		
Eczema	1	0
Erythemas		
Erythema	2	0
Hypertrichoses		
Hirsutism	1	0
Panniculitides		
Erythema nodosum	1	0
Pruritus NEC		
Pruritus	3	0
Rashes, eruptions and exanthems NEC		
Nodular rash	1	0
Rash	4	0
Rash erythematous	3	0
Rash maculo-papular	2	0
Urticarias		
Mechanical urticaria	1	0
Urticaria	7	0
Skin disorders SOC TOTAL	33	0

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Reaction Name	Total	Fatal
Vascular disorders		
Circulatory collapse and shock		
Circulatory collapse	1	0
Peripheral vascular disorders NEC		
Cyanosis	2	0
Flushing	3	0
Vascular disorders SOC TOTAL	6	0
TOTAL REACTIONS FOR DRUG	238	3
TOTAL REPORTS	102	
TOTAL FATAL OUTCOME REPORTS		3