

Case Series Drug Analysis Print

Name: FOI 24/176 Seqirus UK Quadrivalent Influenza Vaccine Analysis Print

Report Run Date: 26-Feb-2024

Data Lock Date: 22-Feb-2024 18:30:04

Earliest Reaction Date: 13-Oct-2021

MedDRA Version: MedDRA 26.1

FOI 24/176 Seqirus UK Quadrivalent Influenza Vaccine Analysis Print: All UK spontaneous suspected Adverse Drug Reaction (ADR) reports associated with the Seqirus UK cell-based Quadrivalent Influenza Vaccine, up to and including 22/02/2024.

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Reaction Name	Total	Fatal
Blood disorders		
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	1	0
Lymphadenopathy	5	0
Blood disorders SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	7	0
<i>Coronary artery disorders NEC</i>		
Arteriosclerosis coronary artery	1	0
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	1	0
Myocardial infarction	1	1
<i>Noninfectious myocarditis</i>		
Myocarditis	1	0
<i>Noninfectious pericarditis</i>		
Pericarditis	2	0
<i>Pericardial disorders NEC</i>		
Pericardial effusion	1	1
Pericardial haemorrhage	1	0
<i>Rate and rhythm disorders NEC</i>		
Extrasystoles	1	0
Tachycardia	1	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	1	0
Ventricular extrasystoles	2	0
Cardiac disorders SOC TOTAL	21	2

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear pain	2	0
Otorrhoea	1	0
<i>Hearing losses</i>		
Deafness	1	0
Deafness transitory	1	0
Deafness unilateral	2	0
Hypoacusis	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	3	0
Vertigo	2	0
Vertigo positional	1	0
Ear disorders SOC TOTAL	14	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Lacrimation disorders</i>		
Dry eye	1	0
Lacrimation increased	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Swelling of eyelid	1	0
<i>Ocular disorders NEC</i>		
Eye disorder	1	0
Eye pain	3	0
Eye swelling	2	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye pruritus	2	0
Ocular hyperaemia	1	0
<i>Ocular sensation disorders</i>		
Asthenopia	1	0
<i>Visual disorders NEC</i>		
Diplopia	1	0
Vision blurred	1	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Visual impairment	1	0
Eye disorders SOC TOTAL	16	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Colitis (excl infective)</i>		
Colitis ulcerative	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	21	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	1	0
Eructation	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	1	0
Flatulence	3	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	1	0
Abdominal pain upper	2	0
Abdominal tenderness	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	1	0
Gastrooesophageal reflux disease	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	2	0
Anal incontinence	1	0
Dysphagia	2	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	21	0
Vomiting	16	0
Vomiting projectile	1	0
<i>Oral soft tissue signs and symptoms</i>		
Paraesthesia oral	2	0
<i>Peritoneal and retroperitoneal disorders</i>		
Ascites	1	0
<i>Tongue signs and symptoms</i>		
Glossodynia	1	0
Swollen tongue	3	0
Gastrointestinal disorders SOC TOTAL	85	0

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Reaction Name	Total	Fatal
General disorders		
<i>Asthenic conditions</i>		
Asthenia	9	0
Fatigue	32	0
Malaise	16	0
<i>Body temperature altered</i>		
Temperature regulation disorder	1	0
<i>Death and sudden death</i>		
Death	6	6
Sudden death	1	1
<i>Febrile disorders</i>		
Pyrexia	18	0
<i>Feelings and sensations NEC</i>		
Chills	21	0
Feeling abnormal	5	0
Feeling cold	3	0
Feeling hot	7	0
Feeling of body temperature change	2	0
<i>Fibrosis NEC</i>		
Fibrosis	1	0
<i>Gait disturbances</i>		
Gait disturbance	2	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	1	0
Influenza like illness	8	0
Peripheral swelling	10	0
Swelling	5	0
Swelling face	2	0
<i>Inflammations</i>		
Inflammation	3	0
<i>Injection site reactions</i>		
Injection site erythema	2	0
Injection site mass	1	0
Injection site pain	5	0
Injection site pruritus	1	0
Injection site swelling	1	0
Injection site urticaria	1	0
<i>Mass conditions NEC</i>		
Nodule	2	0
<i>Pain and discomfort NEC</i>		
Axillary pain	1	0
Chest discomfort	3	0
Chest pain	5	0
Discomfort	1	0
Pain	18	0
Tenderness	1	0
<i>Vaccination site reactions</i>		
Vaccination site bruising	1	0
Vaccination site erythema	8	0
Vaccination site hypoaesthesia	1	0
Vaccination site induration	3	0
Vaccination site irritation	1	0
Vaccination site joint movement impairment	2	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site joint pain	1	0
Vaccination site mass	1	0
Vaccination site pain	12	0
Vaccination site rash	1	0
Vaccination site reaction	1	0
Vaccination site swelling	4	0
Vaccination site vesicles	1	0
Vaccination site warmth	3	0
General disorders SOC TOTAL	235	7

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	1	1
Hepatic necrosis	1	0
Hepatitis	1	0
Hepatic disorders SOC TOTAL	3	1

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	4	0
Multiple allergies	1	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	1	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	1	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	1	0
Immune system disorders SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Infections		
<i>Bacterial infections NEC</i>		
Cellulitis	2	0
<i>Coronavirus infections</i>		
COVID-19	3	0
<i>Ear infections</i>		
Labyrinthitis	1	0
<i>Herpes viral infections</i>		
Herpes zoster	1	0
<i>Infections NEC</i>		
Infection	2	0
Respiratory tract infection	1	0
Vaccine breakthrough infection	1	0
<i>Influenza viral infections</i>		
Influenza	6	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	1	0
Pneumonia	1	1
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	4	0
Rhinitis	1	0
Infections SOC TOTAL	24	1

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Reaction Name	Total	Fatal
Injuries		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	3	0
Exposure via breast milk	1	0
Foetal exposure during pregnancy	1	0
Maternal exposure during breast feeding	2	0
Maternal exposure during pregnancy	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	5	0
<i>Muscle, tendon and ligament injuries</i>		
Muscle strain	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	1	0
<i>Non-site specific injuries NEC</i>		
Wound	1	0
Wound haemorrhage	1	0
<i>Non-site specific procedural complications</i>		
Injection related reaction	1	0
<i>Product administration errors and issues</i>		
Extra dose administered	2	0
Product administered to patient of inappropriate age	8	0
Product administration error	6	0
<i>Product storage errors and issues in the product use system</i>		
Product storage error	3	0
<i>Skin injuries NEC</i>		
Contusion	5	0
Skin laceration	3	0
Injuries SOC TOTAL	45	0

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Reaction Name	Total	Fatal
Investigations		
<i>Heart rate and pulse investigations</i>		
Heart rate increased	3	0
<i>Physical examination procedures and organ system status</i>		
Body temperature abnormal	1	0
Body temperature fluctuation	1	0
Body temperature increased	1	0
<i>Skeletal and cardiac muscle analyses</i>		
Troponin increased	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure diastolic decreased	1	0
Blood pressure increased	1	0
Blood pressure systolic decreased	1	0
Blood pressure systolic increased	1	0
<i>Virus identification and serology</i>		
HIV test false positive	1	0
SARS-CoV-2 test	1	0
Investigations SOC TOTAL	13	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	11	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Metabolic acidosis	1	0
<i>Metabolic disorders NEC</i>		
Metabolic disorder	1	0
<i>Total fluid volume decreased</i>		
Dehydration	1	0
Metabolic disorders SOC TOTAL	14	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Bone related signs and symptoms</i>		
Pain in jaw	1	0
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	2	0
Sjogren's syndrome	1	0
<i>Intervertebral disc disorders NEC</i>		
Intervertebral disc annular tear	1	0
Intervertebral disc protrusion	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	12	0
<i>Muscle infections and inflammations</i>		
Myositis	1	0
<i>Muscle pains</i>		
Myalgia	22	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle fatigue	1	0
Muscle spasms	4	0
Muscle tightness	1	0
Muscle twitching	2	0
<i>Muscle weakness conditions</i>		
Muscular weakness	4	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Mobility decreased	1	0
Musculoskeletal stiffness	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	7	0
Limb discomfort	5	0
Musculoskeletal chest pain	1	0
Neck pain	2	0
Pain in extremity	27	0
<i>Myopathies</i>		
Necrotising myositis	1	0
Rhabdomyolysis	1	0
<i>Osteoarthropathies</i>		
Osteoarthritis	1	0
<i>Spine and neck deformities</i>		
Spinal stenosis	1	0
<i>Spondyloarthropathies</i>		
Arthritis reactive	1	0
Muscle & tissue disorders SOC TOTAL	102	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Neoplasms malignant site unspecified NEC</i>		
Neoplasm malignant	1	0
<i>Paraneoplastic syndromes NEC</i>		
Paraneoplastic syndrome	1	0
Neoplasms SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebrovascular accident	1	0
Lacunar stroke	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	1	0
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	1	0
Loss of consciousness	2	0
Somnolence	1	0
Syncope	6	0
<i>Dyskinesias and movement disorders NEC</i>		
Bradykinesia	1	0
Dyskinesia	2	0
<i>Eye movement disorders</i>		
Vlth nerve disorder	1	0
<i>Headaches NEC</i>		
Cluster headache	2	0
Headache	36	0
Tension headache	1	0
<i>Memory loss (excl dementia)</i>		
Memory impairment	1	0
Transient global amnesia	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Disturbance in attention	2	0
<i>Migraine headaches</i>		
Atypical migraine	1	0
Migraine	2	0
<i>Mononeuropathies</i>		
Nerve compression	2	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	2	0
<i>Neurological signs and symptoms NEC</i>		
Brain fog	1	0
Dizziness	19	0
Head discomfort	1	0
Presyncope	3	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	2	0
Hypoaesthesia	6	0
Paraesthesia	7	0
<i>Peripheral neuropathies NEC</i>		
Neuropathy peripheral	1	0
Peripheral sensory neuropathy	1	0
<i>Seizures and seizure disorders NEC</i>		
Seizure	2	0
<i>Sensory abnormalities NEC</i>		
Ageusia	1	0
Dysgeusia	1	0
Neuralgia	4	0
Sensory disturbance	2	0
<i>Speech and language abnormalities</i>		
Dysarthria	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Spinal cord and nerve root disorders NEC</i>		
Radiculitis brachial	1	0
<i>Transient cerebrovascular events</i>		
Transient ischaemic attack	1	0
<i>Tremor (excl congenital)</i>		
Tremor	2	0
Nervous system disorders SOC TOTAL	123	0

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Gestational age and weight conditions</i>		
Large for dates baby	1	0
<i>Labour onset and length abnormalities</i>		
Prolonged pregnancy	1	0
<i>Maternal complications of delivery NEC</i>		
Traumatic delivery	1	0
<i>Maternal complications of labour NEC</i>		
Intrapartum haemorrhage	1	0
Pregnancy conditions SOC TOTAL	4	0

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Reaction Name	Total	Fatal
<i>Device physical property and chemical issues</i>		
Syringe issue	4	0
null SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Anxiety symptoms</i>		
Nervousness	2	0
<i>Confusion and disorientation</i>		
Confusional state	1	0
<i>Deliria</i>		
Delirium	2	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	4	0
<i>Dyssomnias</i>		
Poor quality sleep	2	0
<i>Emotional and mood disturbances NEC</i>		
Irritability	1	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	3	0
Psychiatric disorders SOC TOTAL	16	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Urinary retention	2	0
<i>Renal failure and impairment</i>		
Acute kidney injury	1	0
Chronic kidney disease	1	0
<i>Renal vascular and ischaemic conditions</i>		
Renal tubular necrosis	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Renal pain	1	0
Renal & urinary disorders SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	9	0
Dyspnoea exertional	1	0
<i>Bronchial conditions NEC</i>		
Bronchial secretion retention	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	1	0
Chronic obstructive pulmonary disease	1	1
Wheezing	1	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Cough	8	0
Productive cough	1	0
<i>Parenchymal lung disorders NEC</i>		
Atelectasis	1	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	1	0
Pneumothorax	1	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	4	1
<i>Respiratory failures (excl neonatal)</i>		
Respiratory failure	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	1	0
Oropharyngeal pain	7	0
Paranasal sinus discomfort	1	0
Rhinalgia	1	0
Rhinorrhoea	6	0
Sinus pain	2	0
Sneezing	1	0
Throat irritation	1	0
Upper-airway cough syndrome	1	0
Respiratory disorders SOC TOTAL	53	2

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Reaction Name	Total	Fatal
Skin disorders		
<i>Angioedemas</i>		
Angioedema	2	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	4	0
Hyperhidrosis	4	0
Night sweats	4	0
<i>Dermal and epidermal conditions NEC</i>		
Skin burning sensation	1	0
Skin lesion	1	0
Skin reaction	2	0
Skin warm	1	0
Skin weeping	1	0
<i>Dermatitis and eczema</i>		
Skin irritation	2	0
<i>Erythemas</i>		
Erythema	18	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Onychalgia	1	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	1	0
<i>Pruritus NEC</i>		
Pruritus	18	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	13	0
Rash erythematous	6	0
Rash macular	3	0
Rash maculo-papular	1	0
Rash papular	3	0
Rash pruritic	3	0
<i>Urticarias</i>		
Urticaria	6	0
Skin disorders SOC TOTAL	95	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Immobile	1	0
Social circumstances SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Obstetric therapeutic procedures</i>		
Caesarean section	1	0
<i>Therapeutic procedures NEC</i>		
Interchange of vaccine products	1	0
Surgical & medical procedures SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Circulatory collapse and shock</i>		
Shock	1	0
<i>Peripheral vascular disorders NEC</i>		
Flushing	1	0
Hot flush	3	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	2	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Orthostatic hypotension	1	0
Vascular disorders SOC TOTAL	10	0
TOTAL REACTIONS FOR DRUG	902	13
TOTAL REPORTS	299	
TOTAL FATAL OUTCOME REPORTS		13