

## Case Series Drug Analysis Print

**Name: FOI 22/1193 - Seqirus UK Quadrivalent Influenza Vaccine  
DAP**

Report Run Date: 10-Jan-2023  
Data Lock Date: 09-Jan-2023 18:30:04  
Earliest Reaction Date: 13-Oct-2021  
MedDRA Version: MedDRA 25.1

FOI 22/1193 - Seqirus UK Quadrivalent Influenza Vaccine DAP: FOI 22/1193 - All spontaneous suspected UK Adverse Drug Reaction (ADR) reports associated with the Seqirus UK Quadrivalent Influenza Vaccine received up to and including 13/12/2022

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	1	0
<b>Blood disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	2	0
<i>Noninfectious pericarditis</i>		
Pericarditis	1	0
<i>Rate and rhythm disorders NEC</i>		
Extrasystoles	1	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>5</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear pain	1	0
<i>Hearing losses</i>		
Deafness transitory	1	0
Deafness unilateral	1	0
<i>Inner ear signs and symptoms</i>		
Vertigo	1	0
<b>Ear disorders SOC TOTAL</b>	<b>4</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<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 pain	1	0
Eye swelling	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Ocular hyperaemia	1	0
<i>Visual disorders NEC</i>		
Vision blurred	1	0
<b>Eye disorders SOC TOTAL</b>	<b>7</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i><b>Diarrhoea (excl infective)</b></i>		
Diarrhoea	11	0
<i><b>Flatulence, bloating and distension</b></i>		
Abdominal distension	1	0
Flatulence	2	0
<i><b>Gastrointestinal and abdominal pains (excl oral and throat)</b></i>		
Abdominal pain	1	0
Abdominal pain upper	1	0
Abdominal tenderness	1	0
<i><b>Gastrointestinal signs and symptoms NEC</b></i>		
Abdominal discomfort	1	0
Anal incontinence	1	0
<i><b>Gastrointestinal spastic and hypermotility disorders</b></i>		
Defaecation urgency	1	0
<i><b>Nausea and vomiting symptoms</b></i>		
Nausea	8	0
Vomiting	6	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>34</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i><b>Asthenic conditions</b></i>		
Asthenia	4	0
Fatigue	20	0
Malaise	4	0
<i><b>Body temperature altered</b></i>		
Temperature regulation disorder	1	0
<i><b>Febrile disorders</b></i>		
Pyrexia	10	0
<i><b>Feelings and sensations NEC</b></i>		
Chills	16	0
Feeling abnormal	1	0
Feeling cold	3	0
Feeling hot	1	0
Feeling of body temperature change	1	0
<i><b>General signs and symptoms NEC</b></i>		
Influenza like illness	5	0
Peripheral swelling	4	0
<i><b>Pain and discomfort NEC</b></i>		
Chest discomfort	3	0
Chest pain	4	0
Pain	10	0
<i><b>Vaccination site reactions</b></i>		
Vaccination site bruising	1	0
Vaccination site erythema	5	0
Vaccination site induration	2	0
Vaccination site irritation	1	0
Vaccination site joint movement impairment	1	0
Vaccination site mass	1	0
Vaccination site pain	8	0
Vaccination site swelling	3	0
Vaccination site warmth	2	0
<b>General disorders SOC TOTAL</b>	<b>111</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Infections</b>		
<i>Bacterial infections NEC</i>		
Cellulitis	1	0
<i>Coronavirus infections</i>		
COVID-19	1	0
<i>Ear infections</i>		
Labyrinthitis	1	0
<i>Infections NEC</i>		
Infection	1	0
<i>Influenza viral infections</i>		
Influenza	4	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	1	0
Rhinitis	1	0
<b>Infections SOC TOTAL</b>	<b>10</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i>Non-site specific injuries NEC</i>		
Wound	1	0
<i>Product administration errors and issues</i>		
Product administered to patient of inappropriate age	1	0
Product administration error	1	0
<i>Skin injuries NEC</i>		
Contusion	1	0
Skin laceration	1	0
<b>Injuries SOC TOTAL</b>	<b>5</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<i>Heart rate and pulse investigations</i>		
Heart rate increased	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature fluctuation	1	0
<b>Investigations SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i>Appetite disorders</i>		
Decreased appetite	7	0
<i>Metabolic disorders NEC</i>		
Metabolic disorder	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>8</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Bone related signs and symptoms</i>		
Pain in jaw	1	0
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	4	0
<i>Muscle pains</i>		
Myalgia	12	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle spasms	2	0
Muscle twitching	2	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Mobility decreased	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	3	0
Limb discomfort	1	0
Musculoskeletal chest pain	1	0
Neck pain	1	0
Pain in extremity	10	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>39</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i><b>Disturbances in consciousness NEC</b></i>		
Loss of consciousness	1	0
Somnolence	1	0
Syncope	4	0
<i><b>Dyskinesias and movement disorders NEC</b></i>		
Dyskinesia	2	0
<i><b>Headaches NEC</b></i>		
Cluster headache	2	0
Headache	23	0
<i><b>Mental impairment (excl dementia and memory loss)</b></i>		
Disturbance in attention	1	0
<i><b>Mononeuropathies</b></i>		
Nerve compression	1	0
<i><b>Narcolepsy and hypersomnia</b></i>		
Hypersomnia	2	0
<i><b>Neurological signs and symptoms NEC</b></i>		
Dizziness	8	0
Head discomfort	1	0
<i><b>Paraesthesias and dysaesthesias</b></i>		
Hypoaesthesia	2	0
Paraesthesia	4	0
<i><b>Seizures and seizure disorders NEC</b></i>		
Seizure	1	0
<i><b>Sensory abnormalities NEC</b></i>		
Sensory disturbance	1	0
<i><b>Tremor (excl congenital)</b></i>		
Tremor	1	0
<b>Nervous system disorders SOC TOTAL</b>	<b>55</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<i>Device physical property and chemical issues</i>		
Syringe issue	2	0
<b>null SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<i>Confusion and disorientation</i>		
Confusional state	1	0
<i>Deliria</i>		
Delirium	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	2	0
<i>Sleep disorders NEC</i>		
Sleep disorder	2	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>6</b>	<b>0</b>



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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Renal &amp; urinary disorders</b>		
<i>Bladder and urethral symptoms</i>		
Urinary retention	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Renal pain	1	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i>Breathing abnormalities</i>		
Dyspnoea	4	0
<i>Coughing and associated symptoms</i>		
Cough	2	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	1	0
Oropharyngeal pain	3	0
Rhinalgia	1	0
Rhinorrhoea	3	0
Sinus pain	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>15</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	1	0
Hyperhidrosis	2	0
Night sweats	2	0
<i>Dermal and epidermal conditions NEC</i>		
Skin lesion	1	0
Skin reaction	1	0
Skin weeping	1	0
<i>Erythemas</i>		
Erythema	5	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	1	0
<i>Pruritus NEC</i>		
Pruritus	5	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	1	0
Rash macular	2	0
Rash papular	2	0
<i>Urticarias</i>		
Urticaria	2	0
<b>Skin disorders SOC TOTAL</b>	<b>26</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i>Circulatory collapse and shock</i>		
Shock	1	0
<i>Peripheral vascular disorders NEC</i>		
Hot flush	1	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>336</b>	<b>0</b>
<b>TOTAL REPORTS</b>	<b>89</b>	