Case Series Drug Analysis Print Name: FOI 21/740 Seqirus

Report Run Date:09-Jul-2021Data Lock Date:08-Jul-2021 18:30:03Earliest Reaction Date:29-Sep-2016MedDRA Version:MedDRA 24.0

FOI 21/740 Seqirus: All spontaneous UK suspected adverse drug reaction reports associated with Seqirus up to and including the 08/07/2021

Name: FOI 21/740 Seqirus

Report Run Date: 09-Jul-2021 Earliest Reaction Date: 29-Sep-2016

Reaction Name	Total	Fatal
Cardiac disorders		
Ventricular arrhythmias and cardiac arrest		
Cardiac arrest	1	1
Cardiac disorders SOC TOTAL	1	1

Name: FOI 21/740 Seqirus

 Report Run Date: 09-Jul-2021
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 Earliest Reaction Date: 29-Sep-2016
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 Reaction Name
 Total
 Fatal

 Ear disorders
 Inner ear signs and symptoms
 Inner

 Vertigo
 1
 0

 Ear disorders SOC TOTAL
 1
 0

Name: FOI 21/740 Seqirus

Report Run Date: 09-Jul-2021 Earliest Reaction Date: 29-Sep-2016

Reaction Name	Total	Fatal
Eye disorders		
Visual impairment and blindness (excl colour blindness)		
Blindness	1	0
Blindness transient	1	0
Visual impairment	1	0
Eve disorders SOC TOTAL	3	0

Name: FOI 21/740 Seqirus

Report Run Date: 09-Jul-2021 Earliest Reaction Date: 29-Sep-2016

Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal pain	1	0
Intestinal haemorrhages		
Rectal haemorrhage	1	0
Nausea and vomiting symptoms		
Nausea	2	0
Vomiting	1	0
Vomiting projectile	1	0
Oral soft tissue signs and symptoms		
Lip erythema	1	0
Paraesthesia oral	1	0
Oral soft tissue swelling and oedema		
Lip swelling	1	0
Gastrointestinal disorders SOC TOTAL	9	0

Name: FOI 21/740 Seqirus

Report Run Date: 09-Jul-2021 Earliest Reaction Date: 29-Sep-2016

Reaction Name	To	tal	Fatal
General disorders			
Asthenic conditions			
Fatigue		2	0
Malaise		3	0
Febrile disorders			
Pyrexia		6	0
Feelings and sensations NEC			
Chills		2	0
Feeling cold		1	0
Feeling hot		2	0
General signs and symptoms NEC			
Influenza like illness		2	0
Peripheral swelling		1	0
Swelling		1	0
Swelling face		1	0
Injection site reactions			
Injected limb mobility decreased		1	0
Injection site pain		2	0
Oedema NEC			
Face oedema		1	0
Pain and discomfort NEC			
Chest discomfort		1	0
Pain		2	0
Vaccination site reactions			
Vaccination site erythema		3	0
Vaccination site mass		1	0
Vaccination site pain		5	0
Vaccination site swelling		4	0
Vaccination site warmth		1	0
General disorders SOC TOTAL		42	0

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Reaction Name		Total	Fatal
Immune system disorders			
Allergic conditions NEC			
Hypersensitivity		3	0
Anaphylactic and anaphylactoid responses			
Anaphylactic reaction		1	0
Immune system disorders SOC TOTAL		4	0

Name: FOI 21/740 Seqirus

Report Run Date: 09-Jul-2021 Earliest Reaction Date: 29-Sep-2016

Reaction Name	Total	Fatal
Infections		
Herpes viral infections		
Herpes zoster	1	0
Upper respiratory tract infections		
Nasopharyngitis	1	0
Sinusitis	1	0
Infections SOC TOTAL	3	0

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Earliest Reaction Date: 29-Sep-2016	MedDRA Version: MedDRA 24.0		
Reaction Name		Total	Fatal
Injuries			
Muscle, tendon and ligament injuries			
Muscle injury		1	0
Injuries SOC TOTAL		1	0

Case Series Drug Analysis Print Name: FOI 21/740 Segirus

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eport Run Date: 09-Jul-2021 Data Lock Date: 08-Jul-2021 18:30:03		
Earliest Reaction Date: 29-Sep-2016	MedDRA Version: MedDRA 24.0	
Reaction Name	Total	Fatal
Metabolic disorders		
Appetite disorders		

Metabolic disorders		
Appetite disorders		
Decreased appetite	1	0
Metabolic disorders SOC TOTAL	1	0

Report Run Date: 09-Jul-2021 Earliest Reaction Date: 29-Sep-2016

Name: FOI 21/740 Seqirus Data Lock Date: 08-Jul-2021 18:30:03 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Arthropathies NEC		
Arthritis	1	0
Joint related signs and symptoms		
Arthralgia	4	0
Joint swelling	1	0
Muscle pains		
Myalgia	2	0
Muscle related signs and symptoms NEC		
Muscle atrophy	1	0
Muscle spasms	1	0
Muscle weakness conditions		
Muscular weakness	3	0
Musculoskeletal and connective tissue conditions NEC		
Musculoskeletal stiffness	2	0
Musculoskeletal and connective tissue pain and discomfort		
Pain in extremity	8	0
Muscle & tissue disorders SOC TOTAL	23	0

Name: FOI 21/740 Seqirus

 Report Run Date: 09-Jul-2021
 Data Lock Date: 08-Jul-2021 18:30:03

 Earliest Reaction Date: 29-Sep-2016
 MedDRA Version: MedDRA 24.0

 Reaction Name
 Total Fatal

 Neoplasms
 Image: Composar comas

 Leiomyosar coma
 1

 Neoplasms SOC TOTAL
 1

Name: FOI 21/740 Seqirus

Report Run Date: 09-Jul-2021 Earliest Reaction Date: 29-Sep-2016 Reaction Name

Data Lock Date: 08-Jul-2021 18:30:03 MedDRA Version: MedDRA 24.0 <u>Total</u>

Fatal

Nervous system disorders		
Abnormal sleep-related events		
Sleep paralysis	1	0
Coordination and balance disturbances		
Ataxia	1	0
Disturbances in consciousness NEC		
Lethargy	1	0
Syncope	4	0
Headaches NEC		
Headache	1	0
Neurologic visual problems NEC		
Tunnel vision	1	0
Neurological signs and symptoms NEC		
Dizziness	3	0
Paraesthesias and dysaesthesias		
Burning sensation	1	0
Hypoaesthesia	1	0
Paraesthesia	2	0
Seizures and seizure disorders NEC		
Seizure	2	0
Speech and language abnormalities		
Dysarthria	1	0
Nervous system disorders SOC TOTAL	19	0

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T	otal	Fatal
	1	0
	1	0
	1	0
	1	0
	4	0
		Total 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1

Name: FOI 21/740 Seqirus

Report Run Date: 09-Jul-2021 Earliest Reaction Date: 29-Sep-2016

Reaction Name	Total	Fatal
Respiratory disorders		
Breathing abnormalities		
Dysphoea	2	0
Coughing and associated symptoms		
Cough	1	0
Upper respiratory tract signs and symptoms		
Rhinorrhoea	1	0
Respiratory disorders SOC TOTAL	4	0

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Report Run Date: 09-Jul-2021 Earliest Reaction Date: 29-Sep-2016

Reaction Name	Total	Fatal
Skin disorders		
Apocrine and eccrine gland disorders		
Hyperhidrosis	3	0
Dermatitis ascribed to specific agent		
Drug eruption	1	0
Erythemas		
Erythema	7	0
Pruritus NEC		
Pruritus	4	0
Purpura and related conditions		
Purpura	1	0
Rashes, eruptions and exanthems NEC		
Rash	3	0
Rash erythematous	1	0
Rash papular	1	0
Rash pruritic	2	0
Urticarias		
Urticaria	3	0
Skin disorders SOC TOTAL	26	0

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