Report Run Date: 07-Oct-2021

Data Lock Date: 30-Sep-2021 18:30:04

Earliest Reaction Date: 08-Nov-1999 MedDRA Version: MedDRA 24.0

Menjugate FOI

21/1063:

All UK spontaneous reports received up until 30-Sep-2021 for the Menjugate vaccine analysis print. A report of a suspected ADR to the Yellow Card scheme does not necessarily mean that it was caused by the vaccine, only that the reporter has a suspicion it may have. Underlying or previously undiagnosed illness unrelated to vaccination can also be factors in such reports. The relative number and nature of reports should therefore not be used to compare the safety of

the different vaccines. All reports are kept under continual review in order to identify possible new risks.

Reaction Name	Total	Fatal
Blood disorders		
Coagulopathies		
Coagulopathy	1	0
Lymphatic system disorders NEC		
Lymphadenopathy	7	7 0
Thrombocytopenias		
Immune thrombocytopenia	2	0
Thrombocytopenia	1	0
Blood disorders SOC TOTAL	11	ا ا

Reaction Name	Total	Fatal
Cardiac disorders		
Cardiac disorders NEC		
Cardiovascular disorder	2	0
Cardiac signs and symptoms NEC		
Palpitations	3	0
Rate and rhythm disorders NEC		
Arrhythmia	1	0
Bradycardia	12	0
Tachycardia	9	0
Cardiac disorders SOC TOTAL	27	0

Reaction Name	Total	Fatal
Congenital disorders		
Cardiac septal defects congenital		
Atrial septal defect	1	0
Congenital disorders SOC TOTAL	1	0

Reaction Name	Total	Fatal
Ear disorders		
Ear disorders NEC		
Ear pain	6	0
Hearing losses		
Deafness transitory	2	2 0
Hypoacusis	4	· 0
Inner ear signs and symptoms		
Tinnitus	11	0
Vertigo	2	2 0
Ear disorders SOC TOTAL	25	<u> </u>

Reaction Name	Total	Fatal
Eve disorders	1	1 0101
Glaucomas (excl congenital)		
Glaucoma	1	0
Lid, lash and lacrimal infections, irritations and inflammations		
Swelling of eyelid	1	0
Ocular disorders NEC		
Eye disorder	1	0
Eye pain	11	0
Eye swelling	8	0
Periorbital oedema	2	0
Ocular infections, inflammations and associated manifestations		
Eye irritation	1	0
Eye pruritus	2	0
Ocular nerve and muscle disorders		
Eye movement disorder	13	0
Ocular sensation disorders		
Abnormal sensation in eye	1	0
Photophobia	20	0
Pupil disorders		
Mydriasis	5	0
Pupils unequal	2	0
Visual disorders NEC		
Diplopia	10	0
Photopsia	6	0
Vision blurred	46	0
Visual impairment and blindness (excl colour blindness)		
Blindness transient	4	0
Visual impairment	6	0
Eve disorders SOC TOTAL	140	0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
Diarrhoea (excl infective)		
Diarrhoea	27	0
Dyspeptic signs and symptoms		
Dyspepsia	1	0
Flatulence, bloating and distension		
Abdominal distension	1	0
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal pain	84	
Abdominal pain upper	102	0
Gastrointestinal atonic and hypomotility disorders NEC		
Constipation	1	0
Gastrointestinal signs and symptoms NEC		
Abdominal discomfort	8	0
Dysphagia	5	0
Gingival disorders, signs and symptoms NEC		
Gingival pain	1	0
Nausea and vomiting symptoms		
Nausea	644	0
Retching	4	0
Vomiting	383	0
Vomiting projectile	1	0
Oral dryness and saliva altered		
Dry mouth	1	0
Salivary hypersecretion	3	0
Oral soft tissue signs and symptoms		
Hypoaesthesia oral	1	0
Lip pain	1	0
Oral soft tissue swelling and oedema		
Lip swelling	5	0
Stomatitis and ulceration		
Mouth ulceration	1	0
Tongue signs and symptoms		
Swollen tongue	2	0
Gastrointestinal disorders SOC TOTAL	1276	0

	MedDRA Version: MedDRA 24.0	
Reaction Name	Total	<u> Fatal</u>
General disorders		
Adverse effect absent		
No adverse event	1	0
Asthenic conditions		
Asthenia	44	I 0
Fatigue	87	7 0
Malaise	428	3 0
Sluggishness	1	ıl ol
Death and sudden death		
Sudden death	1	1
Febrile disorders		
Hyperpyrexia	1	l o
Pyrexia	271	_
Feelings and sensations NEC		
Chills	45	o
Feeling abnormal		. 1
Feeling cold	36	
Feeling drunk		اً ا
Feeling hot	125	_
Feeling of body temperature change	23	
Gait disturbances		Ί Ϋ
Gait disturbance	6	s o
General signs and symptoms NEC		Ί
Condition aggravated	2	2 0
Crepitations		
Crying	29	· •
High-pitched crying	23	
Illness	30	· •
Influenza like illness	24	
Local reaction	209	
Peripheral swelling	369	
Screaming	11	
Swelling	84	
Swelling face	7	
Inflammations		
	53	
Inflammation Injection site reactions	53	9 0
Injection site erythema	E	
	5	
Injection site haemorrhage	125	-
Injection site inflammation		
Injection site mass	20	-
Injection site pain	33	
Injection site rash	21	
Injection site reaction	187	
Injection site swelling	3	9 0
Oedema NEC		
Face oedema		0
Generalised oedema		0
Localised oedema		0
Oedema		0
Oedema peripheral	10	이
Pain and discomfort NEC		
Axillary pain	1	-
Chest discomfort	22	<u> </u>

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Chest pain	18	0
Discomfort	6	0
Pain	47	0
Tenderness	12	0
Therapeutic and nontherapeutic responses		
Drug ineffective	1	0
Vaccination failure	20	0
Vaccination site reactions		
Vaccination site pain	4	0
General disorders SOC TOTAL	2423	1

Reaction Name	Total	Fatal
Immune system disorders		
Allergic conditions NEC		
Hypersensitivity	11	0
Allergies to foods, food additives, drugs and other chemicals		
Reaction to excipient	1	0
Anaphylactic and anaphylactoid responses		
Anaphylactic reaction	18	0
Anaphylactic shock	4	0
Anaphylactoid reaction	2	0
Immune system disorders SOC TOTAL	36	0

	dDRA Version: MedDRA 24.0	
Reaction Name	Total	<u>Fatal</u>
Infections		
Bacterial infections NEC		
Bacterial infection	1	0
Cellulitis	5	5 O
Injection site cellulitis	1	0
Bordetella infections		
Pertussis	1	0
Central nervous system and spinal infections		
Meningitis	2	2 1
Ear infections		
Ear infection	2	2 0
Eye and eyelid infections		
Hordeolum	1	0
Herpes viral infections		
Oral herpes	1	0
Varicella	1	0
Infections NEC		
Infection	3	s o
Injection site abscess	2	
Localised infection	1	0
Vaccination site abscess	2	<u> </u>
Lower respiratory tract and lung infections		
Lower respiratory tract infection	1	0
Neisseria infections		
Meningitis meningococcal	8	3 0
Meningococcal infection	10) o
Meningococcal sepsis	2	2 0
Sepsis, bacteraemia, viraemia and fungaemia N	EC	
Sepsis	1	0
Skin structures and soft tissue infections		
Rash pustular	1	0
Streptococcal infections		
Pneumococcal infection	2	2 0
Tuberculous infections		
Erythema induratum	11	0
Upper respiratory tract infections		
Nasopharyngitis	27	' 0
Pharyngitis		
Tonsillitis	3	2 0
Upper respiratory tract infection	1	O
Viral infections NEC		
Viral infection	1	C
Infections SOC TOTAL	93	

Reaction Name	Total	Fatal
Injuries		
Fractures and dislocations NEC		
Joint dislocation	1	0
Non-site specific injuries NEC		
Fall	3	0
Overdoses NEC		
Overdose	2	0
Product administration errors and issues		
Inappropriate schedule of product administration	1	0
Wrong product administered	1	0
Skin injuries NEC		
Contusion	5	0
Vaccination related complications		
Vaccination complication	1	0
Injuries SOC TOTAL	14	0

Reaction Name	Total	Fatal
Investigations		
Blood gas and acid base analyses		
Oxygen saturation decreased	2	0
Carbohydrate tolerance analyses (incl diabetes)		
Blood glucose decreased	1	0
Heart rate and pulse investigations		
Heart rate decreased	12	0
Heart rate increased	16	0
Heart rate irregular	3	0
Pulse abnormal	28	0
Pulse absent	1	0
Immunology analyses NEC		
Tryptase increased	1	0
Neurologic diagnostic procedures		
Electroencephalogram abnormal	1	0
Physical examination procedures and organ system status		
Body temperature	10	0
Body temperature increased	36	0
Respiratory rate decreased	1	0
Respiratory rate increased	2	0
Weight decreased	1	0
Platelet analyses		
Platelet count decreased	1	0
Protein analyses NEC		
C-reactive protein increased	1	0
Red blood cell analyses		
Haemoglobin decreased	1	0
Renal function analyses		
Blood creatinine decreased	1	0
Blood urea decreased	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure decreased	7	0
Blood pressure increased	2	0
Investigations SOC TOTAL	129	0

Reaction Name	Total	Fatal
Metabolic disorders		
Appetite disorders		
Decreased appetite	13	0
Hypophagia	1	0
Diabetes mellitus (incl subtypes)		
Diabetes mellitus inadequate control	2	0
Type 1 diabetes mellitus	1	0
Food malabsorption and intolerance syndromes (excl sugar intolerance)		
Dairy intolerance	1	0
Food intolerance	1	0
General nutritional disorders NEC		
Feeding disorder	2	0
Food aversion	1	0
Poor feeding infant	3	0
Hypoglycaemic conditions NEC		
Hypoglycaemia	1	0
Metabolic disorders SOC TOTAL	26	0

Earliest Reaction Date: 08-Nov-1999 MedDRA Version: MedDRA 24.0		
Reaction Name	_Total_	<u>Fatal</u>
Muscle & tissue disorders		
Joint related disorders NEC		
Hypermobility syndrome	1	0
Joint related signs and symptoms		
Arthralgia	27	0
Joint stiffness	3	0
Joint swelling	1	0
Muscle pains		
Myalgia	23	0
Muscle related signs and symptoms NEC		
Muscle disorder	2	0
Muscle spasms	4	0
Muscle twitching	52	0
Muscle tone abnormalities		
Floppy infant	2	0
Muscle rigidity	22	0
Muscle weakness conditions		
Muscular weakness	18	0
Musculoskeletal and connective tissue conditions NEC		
Musculoskeletal stiffness	65	0
Toe walking	1	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	18	0
Limb discomfort	8	0
Neck pain	31	0
Pain in extremity	270	0
Spondyloarthropathies		
Arthritis reactive	1	0
Synovial disorders		
Synovitis	1	0
Muscle & tissue disorders SOC TOTAL	550	0

Reaction Name	Total	Fatal
Neoplasms		
Cardiovascular neoplasms benign		
Haemangioma	1	0
Nervous system neoplasms unspecified malignancy NEC		
Astrocytoma	1	0
Skin neoplasms benign		
Haemangioma of skin	1	0
Skin neoplasms malignant and unspecified (excl melanoma)		
Neoplasm skin	2	0
Neoplasms SOC TOTAL	5	0

	edDRA Version: MedDRA 24.0	
Reaction Name	<u>Total</u>	<u>Fatal</u>
Nervous system disorders		
Absence seizures		
Petit mal epilepsy		0
Acute polyneuropathies		
Guillain-Barre syndrome		ı 0
Coordination and balance disturbances		
Balance disorder		0
Coordination abnormal	•	0 ا
Dysstasia	2	2 0
Hand-eye coordination impaired	•	I 0
Cortical dysfunction NEC		
Dyspraxia	•	1 0
Disturbances in consciousness NEC		
Depressed level of consciousness		2 0
Lethargy	33	3 0
Loss of consciousness	30	0
Somnolence	92	2 0
Stupor	•	0 ا
Syncope	590	0
Dyskinesias and movement disorders NEC		
Dyskinesia	27	7 0
Hypokinesia		ı o
Psychomotor hyperactivity		ı o
Dystonias		
Dystonia		ı o
Opisthotonus		ı o
Facial cranial nerve disorders		
Facial paralysis		ı o
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	13	3 0
Headaches NEC		
Headache	109	0 ا
Hydrocephalic conditions		
Hydrocephalus	,	0 ا
Increased intracranial pressure disorders		
Idiopathic intracranial hypertension	,	0 ا
Mental impairment (excl dementia and memory	loss)	
Cognitive disorder	· ·	0 ا
Disturbance in attention		3 0
Migraine headaches		
Migraine	4	4 O
Migraine with aura	,	1 0
Muscle tone abnormal		
Hypotonia		e 0
Neurological signs and symptoms NEC		
Dizziness	1114	ı o
Fontanelle bulging		ı o
Grimacing		0
Meningism		0
Neurological symptom		0
Presyncope	28	
Unresponsive to stimuli		1
Neuromuscular disorders NEC		
Muscle spasticity		0

Reaction Name	Total	Fatal
Nervous system disorders us system disorders cont'd		
Paraesthesias and dysaesthesias		
Burning sensation	2	0
Hyperaesthesia	5	0
Hypoaesthesia	48	0
Paraesthesia	57	0
Partial complex seizures		
Focal dyscognitive seizures	1	0
Seizures and seizure disorders NEC		
Epilepsy	11	0
Seizure	52	0
Seizure anoxic	9	0
Status epilepticus	1	0
Sensory abnormalities NEC		
Dysgeusia	1	0
Sensory disturbance	1	0
Speech and language abnormalities		
Dysarthria	2	0
Speech disorder	2	0
Tremor (excl congenital)		
Tremor	45	0
Nervous system disorders SOC TOTAL	3306	o

Reaction Name	Total	Fatal
Product quality issues NEC		
Product complaint	1	0
null SOC TOTAL	1	l o

Earliest Reaction Date: 08-Nov-1999 MedDRA Version: MedDRA 24.0		
Reaction Name	<u>Total</u>	<u>Fatal</u>
Psychiatric disorders		
Abnormal behaviour NEC		
Abnormal behaviour	2	0
Staring	3	0
Anxiety symptoms		
Agitation	4	0
Anxiety	8	0
Nervousness	24	
Tension	1	0
Behaviour and socialisation disturbances		
Aggression	2	0
Confusion and disorientation		
Confusional state	3	0
Disorientation	7	0
Deliria		
Delirium	6	0
Disturbances in initiating and maintaining sleep		
Insomnia	2	0
Dyssomnias		
Poor quality sleep	1	0
Eating disorders NEC		
Selective eating disorder	1	0
Emotional and mood disturbances NEC		
Emotional distress	5	0
Emotional poverty	1	0
Irritability	13	0
Mood altered	2	0
Fear symptoms and phobic disorders (incl social phobia)		
Social fear	1	0
Fluctuating mood symptoms		
Mood swings	1	0
Hallucinations (excl sleep-related)		
Hallucination	6	0
Increased physical activity levels		
Restlessness	2	0
Mood alterations with depressive symptoms		
Depressed mood	2	0
Tearfulness	6	0
Obsessive-compulsive disorders and symptoms		
Obsessive-compulsive symptom	1	0
Panic attacks and disorders		
Panic attack	3	0
Panic reaction	3	0
Pervasive developmental disorders NEC		
Autism spectrum disorder	1	0
Psychiatric elimination disorders		
Enuresis	1	0
Sleep disorders NEC		
Sleep disorder	2	0
Speech articulation and rhythm disturbances		
Lack of spontaneous speech	1	0
Tic disorders	'	
Tic disorders	1	0
	116	
Psychiatric disorders SOC TOTAL	<u> </u>	

Reaction Name	Total	Fatal
Renal & urinary disorders		
Bladder and urethral symptoms		
Incontinence	3	0
Urinary incontinence	7	0
Glomerulonephritis and nephrotic syndrome		
Glomerulonephritis membranoproliferative	1	0
Nephrotic syndrome	1	0
Urinary abnormalities		
Haematuria	1	0
Renal & urinary disorders SOC TOTAL	13	0

Reaction Name	Total	Fatal
Reproductive & breast disorders		
Reproductive tract signs and symptoms NEC		
Oedema genital	1	0
Reproductive & breast disorders SOC TOTAL	1	0

Reaction Name	Total	Fatal
Respiratory disorders	lotai	<u>i atai</u>
Breathing abnormalities		
Apnoea	2	0
Dyspnoea	24	Ö
Hyperventilation	18	
Hypopnoea	1	Ö
Respiratory arrest	1	Ö
Respiratory distress	1	Ö
Bronchospasm and obstruction	·	Ĭ
Asthma	5	0
Bronchospasm	3	
Wheezing	6	Ö
Conditions associated with abnormal gas exchange		Ĭ
Cyanosis central	2	0
Coughing and associated symptoms		
Cough	12	0
Laryngeal spasm, oedema and obstruction	12	
Laryngospasm	1	0
Stridor	2	0
Nasal congestion and inflammations		
Nasal congestion	1	0
Nasal disorders NEC	· ·	
Epistaxis	5	0
Paranasal sinus disorders (excl infections and neoplasms)		Ĭ
Sinus congestion	1	0
Pharyngeal disorders (excl infections and neoplasms)	·	Ĭ
Pharyngeal oedema	1	0
Pharyngeal swelling	5	Ö
Respiratory tract disorders NEC	J	
Respiratory disorder	1	0
Upper respiratory tract signs and symptoms	· ·	
Choking	2	0
Dry throat	2	Ö
Nasal discomfort	1	0
Oropharyngeal pain	47	
Rhinorrhoea	2	0
Throat irritation	6	0
Throat tightness	17	
Respiratory disorders SOC TOTAL	169	0

	MedDRA Version: MedDRA 24.0	
Reaction Name	Total	Fatal
Skin disorders		
Angioedemas		
Angioedema	2	. 0
Apocrine and eccrine gland disorders		
Cold sweat	148	0
Hyperhidrosis	112	
Miliaria	1	0
Bullous conditions		
Blister	6	0
Erythema multiforme	4	_
Dermal and epidermal conditions NEC		
Dry skin	1	0
Macule	2	
Pain of skin	17	-
Skin burning sensation	'1	
Skin discolouration	10	-
Skin disconfort	1	
Skin induration	13	-
Skin lesion	1	
Skin reaction	g	-
Dermatitis and eczema		
Dermatitis allergic	2	0
Eczema Eczema infantile	3	
		0
Skin irritation	2	. 0
Erythemas	0.10	
Erythema	249	0
Pruritus NEC	0.0	
Pruritus	38	0
Purpura and related conditions		
Petechiae	16	
Purpura	9	0
Rashes, eruptions and exanthems NEC		
Rash	129	
Rash erythematous	16	
Rash macular	50	
Rash maculo-papular	4	. 0
Rash papular		0
Rash pruritic	17	
Rash rubelliform	1	0
Rash vesicular	2	. 0
Skin vasculitides		
Capillaritis	1	0
Skin vasomotor conditions		
Livedo reticularis	6	0
Urticarias		
Urticaria	51	0
Urticaria pigmentosa	1	0
Skin disorders SOC TOTAL	928	l o

Reaction Name	Total	Fatal
Social circumstances		
Disability issues		
Immobile	2	0
Social circumstances SOC TOTAL	2	l o

Reaction Name	Total	Fatal
Surgical & medical procedures		
Induced abortions		
Abortion induced	1	0
Surgical & medical procedures SOC TOTAL	1	0

Reaction Name	Total	Fatal
Vascular disorders	lotai	<u>i alai</u>
Circulatory collapse and shock		
Circulatory collapse	25	0
Shock	6	0
Haemorrhages NEC		
Haemorrhage	1	0
Peripheral vascular disorders NEC		
Cyanosis	25	0
Flushing	59	0
Peripheral vasoconstriction, necrosis and vascular insufficiency		
Peripheral coldness	14	0
Peripheral ischaemia	1	0
Vasoconstriction	2	0
Site specific vascular disorders NEC		
Pallor	454	0
Vascular hypotensive disorders		
Hypotension	10	0
Vascular disorders SOC TOTAL	597	0
TOTAL REACTIONS FOR DRUG	9890	2
TOTAL REPORTS	4479	
TOTAL FATAL OUTCOME REPORTS		2