

Case Series Drug Analysis Print

Name: FOI 21/590 - Menjugate Product Analysis Print

Report Run Date: 29-Jun-2021

Data Lock Date: 08-Apr-2021 18:30:03

Earliest Reaction Date: 08-Nov-1999

MedDRA Version: MedDRA 23.1

FOI 21/590 - All UK, suspected spontaneous reports associated
Menjugate Product with Menjugate up to and including 08/04/2021
Analysis Print:

Case Series Drug Analysis Print

Name: FOI 21/590 - Menjugate Product Analysis Print

Report Run Date: 29-Jun-2021

Data Lock Date: 08-Apr-2021 18:30:03

Earliest Reaction Date: 08-Nov-1999

MedDRA Version: MedDRA 23.1

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

Case Series Drug Analysis Print

Name: FOI 21/590 - Menjugate Product Analysis Print

Report Run Date: 29-Jun-2021

Data Lock Date: 08-Apr-2021 18:30:03

Earliest Reaction Date: 08-Nov-1999

MedDRA Version: MedDRA 23.1

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

Case Series Drug Analysis Print

Name: FOI 21/590 - Menjugate Product Analysis Print

Report Run Date: 29-Jun-2021

Data Lock Date: 08-Apr-2021 18:30:03

Earliest Reaction Date: 08-Nov-1999

MedDRA Version: MedDRA 23.1

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

Case Series Drug Analysis Print

Name: FOI 21/590 - Menjugate Product Analysis Print

Report Run Date: 29-Jun-2021

Data Lock Date: 08-Apr-2021 18:30:03

Earliest Reaction Date: 08-Nov-1999

MedDRA Version: MedDRA 23.1

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

Case Series Drug Analysis Print

Name: FOI 21/590 - Menjugate Product Analysis Print

Report Run Date: 29-Jun-2021

Data Lock Date: 08-Apr-2021 18:30:03

Earliest Reaction Date: 08-Nov-1999

MedDRA Version: MedDRA 23.1

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

Case Series Drug Analysis Print

Name: FOI 21/590 - Menjugate Product Analysis Print

Report Run Date: 29-Jun-2021

Data Lock Date: 08-Apr-2021 18:30:03

Earliest Reaction Date: 08-Nov-1999

MedDRA Version: MedDRA 23.1

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

Case Series Drug Analysis Print

Name: FOI 21/590 - Menjugate Product Analysis Print

Report Run Date: 29-Jun-2021

Data Lock Date: 08-Apr-2021 18:30:03

Earliest Reaction Date: 08-Nov-1999

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
General disorders		
<i>Adverse effect absent</i>		
No adverse event	1	0
<i>Asthenic conditions</i>		
Asthenia	44	0
Fatigue	87	0
Malaise	428	0
Sluggishness	1	0
<i>Death and sudden death</i>		
Sudden death	1	1
<i>Febrile disorders</i>		
Hyperpyrexia	1	0
Pyrexia	271	0
<i>Feelings and sensations NEC</i>		
Chills	45	0
Feeling abnormal	9	0
Feeling cold	36	0
Feeling drunk	1	0
Feeling hot	125	0
Feeling of body temperature change	23	0
<i>Gait disturbances</i>		
Gait disturbance	6	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	2	0
Crepitations	1	0
Crying	29	0
High-pitched crying	1	0
Illness	30	0
Influenza like illness	24	0
Local reaction	209	0
Peripheral swelling	369	0
Screaming	11	0
Swelling	84	0
Swelling face	7	0
<i>Inflammations</i>		
Inflammation	53	0
<i>Injection site reactions</i>		
Injection site erythema	5	0
Injection site haemorrhage	1	0
Injection site inflammation	125	0
Injection site mass	4	0
Injection site pain	33	0
Injection site rash	21	0
Injection site reaction	187	0
Injection site swelling	3	0
<i>Oedema NEC</i>		
Face oedema	1	0
Generalised oedema	1	0
Localised oedema	1	0
Oedema	1	0
Oedema peripheral	10	0
<i>Pain and discomfort NEC</i>		
Axillary pain	1	0
Chest discomfort	22	0

Case Series Drug Analysis Print

Name: FOI 21/590 - Menjugate Product Analysis Print

Report Run Date: 29-Jun-2021

Data Lock Date: 08-Apr-2021 18:30:03

Earliest Reaction Date: 08-Nov-1999

MedDRA Version: MedDRA 23.1

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 site reactions		
Vaccination site pain	4	0
General disorders SOC TOTAL	2403	1

Case Series Drug Analysis Print

Name: FOI 21/590 - Menjugate Product Analysis Print

Report Run Date: 29-Jun-2021

Data Lock Date: 08-Apr-2021 18:30:03

Earliest Reaction Date: 08-Nov-1999

MedDRA Version: MedDRA 23.1

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

Case Series Drug Analysis Print

Name: FOI 21/590 - Menjugate Product Analysis Print

Report Run Date: 29-Jun-2021

Data Lock Date: 08-Apr-2021 18:30:03

Earliest Reaction Date: 08-Nov-1999

MedDRA Version: MedDRA 23.1

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

Case Series Drug Analysis Print

Name: FOI 21/590 - Menjugate Product Analysis Print

Report Run Date: 29-Jun-2021

Data Lock Date: 08-Apr-2021 18:30:03

Earliest Reaction Date: 08-Nov-1999

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Injuries		
<i>Fractures and dislocations NEC</i>		
Joint dislocation	1	0
<i>Non-site specific injuries NEC</i>		
Fall	3	0
<i>Overdoses NEC</i>		
Overdose	2	0
<i>Product administration errors and issues</i>		
Inappropriate schedule of product administration	1	0
Wrong product administered	1	0
<i>Skin injuries NEC</i>		
Contusion	5	0
<i>Vaccination related complications</i>		
Vaccination complication	1	0
Vaccination failure	20	0
Injuries SOC TOTAL	34	0

Case Series Drug Analysis Print

Name: FOI 21/590 - Menjugate Product Analysis Print

Report Run Date: 29-Jun-2021

Data Lock Date: 08-Apr-2021 18:30:03

Earliest Reaction Date: 08-Nov-1999

MedDRA Version: MedDRA 23.1

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

Case Series Drug Analysis Print

Name: FOI 21/590 - Menjugate Product Analysis Print

Report Run Date: 29-Jun-2021

Data Lock Date: 08-Apr-2021 18:30:03

Earliest Reaction Date: 08-Nov-1999

MedDRA Version: MedDRA 23.1

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

Case Series Drug Analysis Print

Name: FOI 21/590 - Menjugate Product Analysis Print

Report Run Date: 29-Jun-2021
 Earliest Reaction Date: 08-Nov-1999

Data Lock Date: 08-Apr-2021 18:30:03
 MedDRA Version: MedDRA 23.1

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

Case Series Drug Analysis Print

Name: FOI 21/590 - Menjugate Product Analysis Print

Report Run Date: 29-Jun-2021

Data Lock Date: 08-Apr-2021 18:30:03

Earliest Reaction Date: 08-Nov-1999

MedDRA Version: MedDRA 23.1

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

Case Series Drug Analysis Print

Name: FOI 21/590 - Menjugate Product Analysis Print

Report Run Date: 29-Jun-2021

Data Lock Date: 08-Apr-2021 18:30:03

Earliest Reaction Date: 08-Nov-1999

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Absence seizures</i>		
Petit mal epilepsy	6	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	6	0
Coordination abnormal	1	0
Dysstasia	2	0
Hand-eye coordination impaired	1	0
<i>Cortical dysfunction NEC</i>		
Dyspraxia	1	0
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	2	0
Lethargy	33	0
Loss of consciousness	30	0
Somnolence	92	0
Stupor	1	0
Syncope	590	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	27	0
Hypokinesia	1	0
Psychomotor hyperactivity	1	0
<i>Dystonias</i>		
Dystonia	1	0
Opisthotonus	1	0
<i>Facial cranial nerve disorders</i>		
Facial paralysis	1	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	13	0
<i>Headaches NEC</i>		
Headache	1091	0
<i>Hydrocephalic conditions</i>		
Hydrocephalus	1	0
<i>Increased intracranial pressure disorders</i>		
Idiopathic intracranial hypertension	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	1	0
Disturbance in attention	3	0
<i>Migraine headaches</i>		
Migraine	4	0
Migraine with aura	1	0
<i>Muscle tone abnormal</i>		
Hypotonia	9	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	1111	0
Fontanelle bulging	1	0
Grimacing	1	0
Meningism	2	0
Neurological symptom	1	0
Presyncope	28	0
Unresponsive to stimuli	2	0
<i>Neuromuscular disorders NEC</i>		
Muscle spasticity	1	0

Case Series Drug Analysis Print

Name: FOI 21/590 - Menjugate Product Analysis Print

Report Run Date: 29-Jun-2021
 Earliest Reaction Date: 08-Nov-1999

Data Lock Date: 08-Apr-2021 18:30:03
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	2	0
Hyperaesthesia	5	0
Hypoaesthesia	48	0
Paraesthesia	57	0
<i>Partial complex seizures</i>		
Focal dyscognitive seizures	1	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	11	0
Seizure	52	0
Seizure anoxic	9	0
Status epilepticus	1	0
<i>Sensory abnormalities NEC</i>		
Dysgeusia	1	0
Sensory disturbance	1	0
<i>Sleep disturbances NEC</i>		
Poor quality sleep	1	0
<i>Speech and language abnormalities</i>		
Dysarthria	2	0
Speech disorder	2	0
<i>Tremor (excl congenital)</i>		
Tremor	45	0
Nervous system disorders SOC TOTAL	3307	0

Case Series Drug Analysis Print

Name: FOI 21/590 - Menjugate Product Analysis Print

Report Run Date: 29-Jun-2021

Data Lock Date: 08-Apr-2021 18:30:03

Earliest Reaction Date: 08-Nov-1999

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<i>Product quality issues NEC</i>		
Product complaint	1	0
null SOC TOTAL	1	0

Case Series Drug Analysis Print

Name: FOI 21/590 - Menjugate Product Analysis Print

Report Run Date: 29-Jun-2021

Data Lock Date: 08-Apr-2021 18:30:03

Earliest Reaction Date: 08-Nov-1999

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	2	0
Staring	3	0
<i>Anxiety symptoms</i>		
Agitation	4	0
Anxiety	8	0
Nervousness	24	0
Tension	1	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	2	0
<i>Confusion and disorientation</i>		
Confusional state	3	0
Disorientation	7	0
<i>Deliria</i>		
Delirium	6	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	2	0
<i>Eating disorders NEC</i>		
Selective eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Emotional distress	5	0
Emotional poverty	1	0
Irritability	13	0
Mood altered	2	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Social fear	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	6	0
<i>Increased physical activity levels</i>		
Restlessness	2	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	2	0
Tearfulness	6	0
<i>Obsessive-compulsive disorders and symptoms</i>		
Obsessive-compulsive symptom	1	0
<i>Panic attacks and disorders</i>		
Panic attack	3	0
Panic reaction	3	0
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	1	0
<i>Psychiatric elimination disorders</i>		
Enuresis	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	2	0
<i>Speech articulation and rhythm disturbances</i>		
Lack of spontaneous speech	1	0
<i>Tic disorders</i>		
Tic	1	0
Psychiatric disorders SOC TOTAL	115	0

Case Series Drug Analysis Print

Name: FOI 21/590 - Menjugate Product Analysis Print

Report Run Date: 29-Jun-2021

Data Lock Date: 08-Apr-2021 18:30:03

Earliest Reaction Date: 08-Nov-1999

MedDRA Version: MedDRA 23.1

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

Case Series Drug Analysis Print

Name: FOI 21/590 - Menjugate Product Analysis Print

Report Run Date: 29-Jun-2021

Data Lock Date: 08-Apr-2021 18:30:03

Earliest Reaction Date: 08-Nov-1999

MedDRA Version: MedDRA 23.1

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

Case Series Drug Analysis Print

Name: FOI 21/590 - Menjugate Product Analysis Print

Report Run Date: 29-Jun-2021
Earliest Reaction Date: 08-Nov-1999

Data Lock Date: 08-Apr-2021 18:30:03
MedDRA Version: MedDRA 23.1

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

Case Series Drug Analysis Print

Name: FOI 21/590 - Menjugate Product Analysis Print

Report Run Date: 29-Jun-2021

Data Lock Date: 08-Apr-2021 18:30:03

Earliest Reaction Date: 08-Nov-1999

MedDRA Version: MedDRA 23.1

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

Case Series Drug Analysis Print

Name: FOI 21/590 - Menjugate Product Analysis Print

Report Run Date: 29-Jun-2021

Data Lock Date: 08-Apr-2021 18:30:03

Earliest Reaction Date: 08-Nov-1999

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Immobile	2	0
Social circumstances SOC TOTAL	2	0

Case Series Drug Analysis Print

Name: FOI 21/590 - Menjugate Product Analysis Print

Report Run Date: 29-Jun-2021

Data Lock Date: 08-Apr-2021 18:30:03

Earliest Reaction Date: 08-Nov-1999

MedDRA Version: MedDRA 23.1

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

Case Series Drug Analysis Print

Name: FOI 21/590 - Menjugate Product Analysis Print

Report Run Date: 29-Jun-2021

Data Lock Date: 08-Apr-2021 18:30:03

Earliest Reaction Date: 08-Nov-1999

MedDRA Version: MedDRA 23.1

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