

Reaction SOC	Reaction PT	Buserelin		
		European Economic Area	Non European Economic Area	Total
Blood	Anaemia	2	1	3
	Aplastic anaemia	0	2	2
	Eosinophilia	0	1	1
	Haemolysis	1	0	1
	Haemorrhagic disorder	0	1	1
	Leukopenia	1	2	3
	Thrombocytopenia	0	10	10
Card	Angina pectoris	0	2	2
	Arrhythmia	3	2	5
	Atrial fibrillation	1	0	1
	Atrial flutter	1	0	1
	Bradycardia	2	1	3
	Cardiac arrest	1	0	1
	Cardiac failure	0	1	1
	Cardiac failure congestive	0	1	1
	Cardio-respiratory arrest	1	1	2
	Cardiomyopathy	0	1	1
	Cyanosis	0	3	3
	Mitral valve disease	0	1	1
	Myocardial infarction	0	5	5
	Palpitations	0	4	4
	Pericardial effusion	1	0	1
	Prinzmetal angina	0	1	1
	Stress cardiomyopathy	0	1	1
	Tachycardia	1	0	1
	Ventricular tachycardia	0	1	1
Cong	Heart disease congenital	0	1	1
	Kidney malformation	1	0	1
	Testicular dysplasia	0	1	1
	Trisomy 21	0	1	1
	Urinary tract malformation	1	0	1
Ear	Ear discomfort	0	1	1
	Hearing impaired	1	0	1
	Meniere's disease	1	0	1
	Sudden hearing loss	1	0	1
	Tinnitus	0	1	1
	Vertigo	2	0	2
Endo	Basedow's disease	0	2	2
	Goitre	0	1	1
	Hyperthyroidism	0	1	1
Eye	Abnormal sensation in eye	2	0	2
	Asthenopia	0	1	1
	Astigmatism	0	1	1
	Blindness	1	1	2
	Conjunctivitis	0	1	1
	Eyelid ptosis	0	1	1
	Gaze palsy	0	2	2
	Macular degeneration	1	1	2
	Ocular hyperaemia	0	2	2
	Papilloedema	1	0	1
	Retinal detachment	0	2	2
	Retinal haemorrhage	0	1	1
	Retinal vein thrombosis	2	0	2
	Retinitis	0	1	1
	Scleral haemorrhage	0	1	1
	Vision blurred	1	1	2
	Visual impairment	3	2	5
	Abdominal discomfort	1	0	1
	Abdominal distension	3	2	5
	Abdominal pain	3	5	8
	Abdominal pain lower	0	4	4
	Abdominal pain upper	0	1	1
	Anal sphincter atony	1	0	1
	Ascites	4	4	8
	Constipation	1	0	1
	Diarrhoea	1	0	1

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		European Economic Area	Non European Economic Area	Total
Gastr	Dysphagia	2	0	2
	Eructation	1	0	1
	Gastric ulcer	0	1	1
	Gastritis	0	1	1
	Gastrointestinal disorder	1	0	1
	Gastrointestinal hypomotility	1	0	1
	Lip swelling	1	0	1
	Nausea	3	10	13
	Pancreatitis acute	0	1	1
	Paraesthesia oral	1	0	1
	Rectal haemorrhage	0	1	1
	Retching	0	1	1
	Swollen tongue	1	0	1
	Tongue eruption	1	0	1
	Vomiting	3	10	13
Genrl	Abasia	0	1	1
	Application site haematoma	0	1	1
	Asthenia	1	0	1
	Chest discomfort	0	2	2
	Chest pain	2	3	5
	Chills	0	2	2
	Condition aggravated	3	0	3
	Death	5	1	6
	Disease progression	1	1	2
	Drug ineffective	0	1	1
	Drug interaction	1	0	1
	Face oedema	1	0	1
	Fatigue	1	2	3
	Feeling abnormal	0	3	3
	Gait disturbance	1	1	2
	General symptom	1	0	1
	Generalised oedema	1	1	2
	Injection site erythema	1	2	3
	Injection site pruritus	0	1	1
	Injection site swelling	0	1	1
	Irritability	0	1	1
	Malaise	0	4	4
	Multi-organ failure	0	1	1
	Oedema	2	2	4
	Oedema peripheral	3	4	7
	Pain	0	1	1
	Pyrexia	2	7	9
	Swelling	1	0	1
Hepat	Autoimmune hepatitis	0	1	1
	Cholestasis	1	0	1
	Drug-induced liver injury	1	0	1
	Hepatic function abnormal	0	6	6
	Hepatitis	1	0	1
	Hyperbilirubinaemia	1	0	1
	Jaundice	1	1	2
Immun	Anaphylactic reaction	1	3	4
	Anaphylactic shock	0	4	4
	Anaphylactoid reaction	0	2	2
	Corneal graft rejection	0	1	1
	Hypersensitivity	6	0	6
	Serum sickness	0	1	1
Infec	Cellulitis	0	2	2
	Infectious peritonitis	0	1	1
	Injection site abscess	0	1	1
	Meningitis	1	0	1
	Oral herpes	1	0	1
	Sepsis	0	1	1
	Urinary tract infection	1	0	1
	Vestibular neuronitis	1	0	1
	Foetal exposure during pregnancy	1	1	2
	Foetal exposure timing unspecified	0	1	1

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Inj&P	Maternal exposure during pregnancy	1	1	2
	Medication error	0	1	1
	Tendon rupture	0	1	1
	Thoracic vertebral fracture	0	1	1
Inv	Alanine aminotransferase increased	1	3	4
	Alpha 1 foetoprotein normal	1	0	1
	Anti-cyclic citrullinated peptide antibody positive	1	0	1
	Antinuclear antibody positive	1	0	1
	Aspartate aminotransferase increased	0	2	2
	Blood alkaline phosphatase increased	2	1	3
	Blood bilirubin increased	1	0	1
	Blood creatine phosphokinase increased	1	1	2
	Blood glucose increased	0	2	2
	Blood lactate dehydrogenase increased	0	2	2
	Blood potassium increased	0	1	1
	Blood pressure decreased	1	2	3
	Blood pressure increased	1	3	4
	Blood testosterone increased	0	2	2
	C-reactive protein increased	0	1	1
	Carbohydrate antigen 125 increased	0	1	1
	Electrocardiogram abnormal	0	1	1
	Electrocardiogram ST segment elevation	0	1	1
	Eosinophil count increased	0	1	1
	Gamma-glutamyltransferase increased	1	1	2
	Glycosylated haemoglobin increased	0	1	1
	Haemoglobin decreased	0	2	2
	Heart rate decreased	0	1	1
	Hepatic enzyme increased	1	0	1
	Liver function test abnormal	1	0	1
	Platelet count decreased	0	2	2
	Prothrombin time prolonged	1	0	1
	Red blood cell count decreased	0	2	2
	Red blood cell sedimentation rate increased	1	0	1
	Transaminases increased	3	0	3
	Urine output decreased	0	2	2
	Weight decreased	2	2	4
	Weight increased	1	2	3
	White blood cell count decreased	0	4	4
	White blood cell count increased	0	2	2
Metab	Decreased appetite	1	1	2
	Diabetes mellitus	2	3	5
	Fluid retention	1	0	1
	Hypercholesterolaemia	0	2	2
	Hyperglycaemia	1	1	2
	Hypocalcaemia	0	1	1
	Increased appetite	0	1	1
	Tetany	0	1	1
Musc	Type 1 diabetes mellitus	0	1	1
	Arthralgia	1	3	4
	Back pain	1	1	2
	Bone pain	3	0	3
	Epiphysiolysis	2	0	2
	Joint stiffness	0	1	1
	Joint swelling	1	0	1
	Juvenile arthritis	1	0	1
	Knee deformity	1	0	1
	Mastication disorder	2	0	2
	Muscle atrophy	1	0	1
	Muscle spasms	1	3	4
	Muscular weakness	2	2	4
	Musculoskeletal pain	1	0	1
	Musculoskeletal stiffness	1	2	3
	Myalgia	3	1	4
	Osteonecrosis	0	1	1
	Osteonecrosis of jaw	1	0	1
	Osteopenia	0	1	1

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	Osteoporosis	0	2	2
	Pain in extremity	2	5	7
	Polychondritis	0	1	1
	Primary sequestrum	1	0	1
	Rheumatoid arthritis	2	0	2
	Rotator cuff syndrome	0	1	1
Neopl	Adult T-cell lymphoma/leukaemia	0	1	1
	Brain neoplasm	0	1	1
	Breast cancer	0	3	3
	Degeneration of uterine leiomyoma	0	1	1
	Endometrial cancer	0	1	1
	Gestational trophoblastic tumour	1	0	1
	Hepatic neoplasm	0	1	1
	Hepatic neoplasm malignant	1	0	1
	Histiocytosis haematophagic	0	1	1
	Leukaemia	1	0	1
	Meningioma	0	1	1
	Neoplasm	0	1	1
	Ovarian cancer	0	1	1
	Ovarian epithelial cancer	0	1	1
	Phaeochromocytoma	0	1	1
	Pituitary tumour benign	0	1	1
	Sarcoma	0	1	1
	Uterine leiomyoma	0	1	1
Nerv	Ageusia	2	0	2
	Altered state of consciousness	0	1	1
	Amnesia	0	1	1
	Anosmia	1	0	1
	Aphasia	1	1	2
	Areflexia	1	0	1
	Balance disorder	1	0	1
	Benign intracranial hypertension	1	0	1
	Brain stem haemorrhage	0	1	1
	Burning sensation	1	0	1
	Carpal tunnel syndrome	0	1	1
	Cerebral artery stenosis	0	1	1
	Cerebral infarction	1	7	8
	Cerebral ischaemia	1	0	1
	Cerebral thrombosis	1	0	1
	Cerebral vasoconstriction	0	1	1
	Cerebrovascular accident	0	1	1
	Clonic convulsion	1	0	1
	Convulsion	0	2	2
	Depressed level of consciousness	0	1	1
	Dizziness	4	5	9
	Dizziness postural	0	1	1
	Dysgeusia	0	1	1
	Epilepsy	0	1	1
	Facial nerve disorder	0	1	1
	Facial paresis	1	0	1
	Guillain-Barre syndrome	1	0	1
	Headache	0	14	14
	Hemiparesis	0	1	1
	Horner's syndrome	1	0	1
	Hyperaesthesia	2	0	2
	Hypertensive encephalopathy	0	1	1
	Hypoaesthesia	0	1	1
	Hypokinesia	1	0	1
	Incoherent	0	1	1
	Lacunar infarction	0	1	1
	Loss of consciousness	0	2	2
	Migraine	1	1	2
	Multiple sclerosis	1	0	1
	Myelitis transverse	1	0	1
	Neuropathy peripheral	0	1	1
	Nystagmus	1	1	2

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	Optic neuritis	1	0	1
	Paraesthesia	4	0	4
	Paralysis	1	1	2
	Parkinsonian gait	1	0	1
	Parosmia	1	1	2
	Progressive supranuclear palsy	0	1	1
	Quadriplegia	1	0	1
	Sensory disturbance	1	0	1
	Sensory loss	0	1	1
	Somnolence	0	1	1
	Spinal cord compression	1	0	1
	Spinal cord disorder	1	0	1
	Status epilepticus	1	0	1
	Stupor	0	2	2
	Subarachnoid haemorrhage	0	1	1
	Syncope	0	1	1
	Transient ischaemic attack	0	1	1
	VIIth nerve paralysis	7	1	8
	Visual field defect	0	1	1
Preg	Abortion	0	1	1
	Abortion missed	0	3	3
	Abortion spontaneous	1	2	3
	Ectopic pregnancy	2	1	3
	Foetal death	1	0	1
	Foetal growth restriction	1	0	1
	Pregnancy	0	4	4
	Ruptured ectopic pregnancy	1	0	1
Psych	Twin pregnancy	0	1	1
	Agitation	1	1	2
	Anxiety	1	1	2
	Completed suicide	0	1	1
	Depression	1	7	8
	Hallucination	1	0	1
	Insomnia	1	3	4
	Mood swings	1	0	1
	Psychotic disorder	1	0	1
Renal	Suicide attempt	0	1	1
	Thinking abnormal	0	1	1
	Anuria	0	1	1
	Detrusor sphincter dyssynergia	1	0	1
	Dysuria	1	0	1
	Glomerulonephritis	1	0	1
	Pollakiuria	1	0	1
	Renal failure acute	0	3	3
Repro	Tubulointerstitial nephritis	0	1	1
	Urinary retention	2	0	2
	Amenorrhoea	0	2	2
	Endometriosis	0	1	1
	Genital haemorrhage	0	2	2
	Gynaecomastia	1	0	1
	Menopausal symptoms	0	2	2
	Metrorrhagia	0	11	11
	Ovarian cyst	0	2	2
	Ovarian cyst ruptured	0	2	2
	Ovarian enlargement	0	5	5
	Ovarian hyperstimulation syndrome	10	13	23
	Testicular atrophy	2	0	2
	Vulval oedema	0	1	1
	Alveolitis allergic	1	0	1
	Bronchospasm	0	1	1
	Cough	2	2	4
	Dyspnoea	5	11	16
	Laryngeal oedema	1	0	1
	Nasal congestion	0	1	1
	Oropharyngeal discomfort	0	1	1
	Pleural effusion	0	1	1

Reaction SOC	Reaction PT	Buserelin		
		European Economic Area	Non European Economic Area	Total
Resp	Pulmonary alveolar haemorrhage	0	1	1
	Pulmonary embolism	1	2	3
	Pulmonary eosinophilia	1	0	1
	Pulmonary fibrosis	1	0	1
	Respiratory disorder	1	0	1
	Respiratory distress	2	0	2
	Rhinalgia	0	1	1
	Rhinorrhoea	0	1	1
	Suffocation feeling	1	0	1
	Tachypnoea	0	1	1
Skin	Acne	1	0	1
	Alopecia	0	4	4
	Angioedema	0	1	1
	Blister	1	0	1
	Dermal cyst	1	0	1
	Drug eruption	0	2	2
	Dry skin	0	1	1
	Ecchymosis	0	1	1
	Erythema	1	3	4
	Erythema multiforme	1	1	2
	Haemorrhage subcutaneous	0	1	1
	Hyperhidrosis	3	2	5
	Nail discolouration	0	1	1
	Pemphigoid	1	0	1
	Photosensitivity reaction	1	0	1
	Pruritus	2	2	4
	Pruritus generalised	1	0	1
	Purpura	0	2	2
	Rash	1	4	5
	Rash vesicular	1	0	1
	Skin burning sensation	1	0	1
	Skin discolouration	0	1	1
	Skin necrosis	1	0	1
	Urticaria	3	6	9
SocCi	Activities of daily living impaired	1	0	1
Surg	Sequestrectomy	1	0	1
Vasc	Deep vein thrombosis	0	1	1
	Hot flush	3	4	7
	Hypertension	2	7	9
	Hypertensive crisis	0	1	1
	Hypotension	0	2	2
	Jugular vein thrombosis	0	1	1
	Lymphoedema	1	0	1
	Malignant hypertension	0	1	1
	Pallor	0	1	1
	Peripheral coldness	0	1	1
	Peripheral embolism	0	1	1
	Shock	0	2	2
	Shock haemorrhagic	0	1	1
	Temporal arteritis	1	0	1
	Thrombophlebitis	0	1	1
	Thrombosis	1	1	2
	Vasodilatation	0	1	1
	Venous thrombosis limb	0	1	1