

Reaction SOC	Reaction PT	Leuprorelin			
		European Economic Area	Non European Economic Area	Not Specified	Total
Blood	Acquired haemophilia with anti FVIII, XI, or XIII	0	1	0	1
	Anaemia	10	88	0	98
	Anaemia haemolytic autoimmune	0	1	0	1
	Anaemia neonatal	1	0	0	1
	Anaemia of chronic disease	0	1	0	1
	Anaemia vitamin B12 deficiency	0	3	0	3
	Aplasia pure red cell	0	1	0	1
	Aplastic anaemia	2	14	0	16
	Bone marrow disorder	0	2	0	2
	Bone marrow failure	0	13	0	13
	Bone marrow oedema	1	0	0	1
	Bone marrow oedema syndrome	0	2	0	2
	Coagulopathy	1	4	0	5
	Disseminated intravascular coagulation	2	36	0	38
	Eosinophilia	6	5	0	11
	Febrile neutropenia	0	3	0	3
	Haemolysis	1	2	0	3
	Haemolytic anaemia	1	15	0	16
	Haemolytic uraemic syndrome	1	0	0	1
	Haemorrhagic anaemia	0	2	0	2
	Haemorrhagic diathesis	0	4	0	4
	Hilar lymphadenopathy	0	1	0	1
	Hypereosinophilic syndrome	1	0	0	1
	Hypergammaglobulinaemia	0	1	0	1
	Hypochromic anaemia	0	5	0	5
	Idiopathic thrombocytopenic purpura	0	5	0	5
	Iron deficiency anaemia	0	7	0	7
	Leukocytosis	1	5	0	6
	Leukopenia	3	26	0	29
	Lymphadenitis	0	1	0	1
	Lymphadenopathy	1	11	0	12
	Lymphadenopathy mediastinal	0	4	0	4
	Lymphocytic infiltration	0	1	0	1
	Lymphocytosis	0	1	0	1
	Mastocytosis	1	0	0	1
	Monocytosis	0	1	0	1
	Nephrogenic anaemia	0	2	0	2
	Neutropenia	2	12	0	14
	Neutrophilia	1	0	0	1
	Normochromic normocytic anaemia	3	3	0	6
	Pancytopenia	0	27	0	27
	Polycythaemia	0	3	0	3
	Spleen disorder	0	1	0	1
	Splenic vein thrombosis	0	2	0	2
Thrombocytopenia	8	45	1	54	
Thrombocytopenic purpura	0	2	0	2	
Thrombocytosis	1	1	0	2	
Thymus disorder	0	2	0	2	
White blood cell disorder	0	1	0	1	
Acute coronary syndrome	2	0	0	2	
Acute myocardial infarction	2	14	0	16	
Angina pectoris	2	15	0	17	
Angina unstable	0	3	0	3	
Aortic valve disease	0	1	0	1	
Arrhythmia	2	23	0	25	
Arrhythmia supraventricular	0	1	0	1	
Atrial fibrillation	2	18	0	20	
Atrial flutter	0	1	0	1	
Atrial tachycardia	0	2	0	2	
Atrioventricular block	0	3	0	3	
Atrioventricular block complete	1	4	0	5	
Atrioventricular block first degree	0	1	0	1	
Bradycardia	3	7	0	10	
Bundle branch block left	0	1	0	1	

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Card	Bundle branch block right	0	3	0	3
	Cardiac arrest	3	16	0	19
	Cardiac disorder	1	12	0	13
	Cardiac failure	6	51	0	57
	Cardiac failure acute	0	10	0	10
	Cardiac failure congestive	0	32	0	32
	Cardiac fibrillation	0	2	0	2
	Cardiac hypertrophy	0	1	0	1
	Cardiac tamponade	0	3	0	3
	Cardiac valve disease	0	2	0	2
	Cardio-respiratory arrest	0	8	0	8
	Cardiogenic shock	1	0	0	1
	Cardiomegaly	0	8	0	8
	Cardiomyopathy	0	2	0	2
	Cardiovascular disorder	4	4	0	8
	Cor pulmonale	0	1	0	1
	Coronary artery disease	1	0	0	1
	Coronary artery embolism	0	1	0	1
	Coronary artery occlusion	1	4	0	5
	Coronary artery stenosis	0	2	0	2
	Coronary artery thrombosis	0	4	0	4
	Cyanosis	1	17	0	18
	Diastolic dysfunction	0	2	0	2
	Dilatation atrial	0	1	0	1
	Dilatation ventricular	0	1	0	1
	Extrasystoles	2	1	0	3
	Haemorrhage coronary artery	0	1	0	1
	Heart valve incompetence	0	1	0	1
	Heart valve stenosis	0	2	0	2
	Intracardiac thrombus	0	2	0	2
	Left atrial dilatation	0	4	0	4
	Left ventricular dysfunction	0	2	0	2
	Left ventricular failure	0	1	0	1
	Left ventricular hypertrophy	0	1	0	1
	Mitral valve incompetence	0	4	0	4
	Mitral valve stenosis	0	2	0	2
	Myocardial infarction	8	67	0	75
	Myocardial ischaemia	0	7	0	7
	Nodal arrhythmia	0	1	0	1
	Palpitations	6	43	0	49
	Pericardial effusion	0	5	0	5
	Pericarditis	0	2	0	2
	Postural orthostatic tachycardia syndrome	0	1	0	1
	Prinzmetal angina	0	1	0	1
	Pulmonary valve incompetence	0	1	0	1
	Right ventricular failure	0	5	0	5
	Sick sinus syndrome	0	1	0	1
	Sinus bradycardia	0	2	0	2
	Sinus tachycardia	1	5	0	6
	Stress cardiomyopathy	0	2	0	2
	Supraventricular extrasystoles	0	4	0	4
	Supraventricular tachycardia	0	2	0	2
	Tachyarrhythmia	0	3	0	3
	Tachycardia	6	48	0	54
	Torsade de pointes	0	3	0	3
	Tricuspid valve incompetence	0	2	0	2
	Ventricular arrhythmia	0	1	0	1
	Ventricular extrasystoles	1	15	0	16
	Ventricular fibrillation	1	1	0	2
	Ventricular hypertrophy	0	2	0	2
Ventricular hypokinesia	0	2	0	2	
Ventricular tachycardia	1	7	0	8	
Arnold-Chiari malformation	0	1	0	1	
Arteriovenous malformation	0	2	0	2	

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Cong	Birth mark	1	0	0	1
	Cleft lip	0	2	0	2
	Cleft lip and palate	0	1	0	1
	Cleft palate	0	4	0	4
	Colour blindness	0	1	0	1
	Congenital anomaly	0	4	0	4
	Congenital arterial malformation	0	1	0	1
	Congenital eye disorder	1	0	0	1
	Congenital foot malformation	1	0	0	1
	Congenital genital malformation	0	2	0	2
	Congenital genital malformation female	0	1	0	1
	Congenital genitourinary abnormality	0	1	0	1
	Congenital hand malformation	0	1	0	1
	Congenital heart valve disorder	0	2	0	2
	Congenital multiplex arthrogyrosis	0	1	0	1
	Congenital musculoskeletal anomaly	0	2	0	2
	Congenital scoliosis	0	1	0	1
	Cryptorchism	0	3	0	3
	Cytogenetic abnormality	0	3	0	3
	Dermoid cyst	1	0	0	1
	Factor VIII deficiency	0	1	0	1
	Genitalia external ambiguous	0	1	0	1
	Heart disease congenital	0	1	0	1
	Homocystinaemia	0	1	0	1
	Hypoplastic left heart syndrome	0	1	0	1
	Limb malformation	0	1	0	1
	Limb reduction defect	0	1	0	1
	Multiple congenital abnormalities	0	1	0	1
	Neural tube defect	0	1	0	1
	Phimosis	0	3	0	3
	Pierre Robin syndrome	0	1	0	1
	Porphyria acute	0	1	0	1
	Porphyria non-acute	2	0	0	2
	Pyloric stenosis	0	2	0	2
	Reproductive tract hypoplasia, male	0	1	0	1
	Sex chromosome abnormality	3	0	0	3
	Skull malformation	0	1	0	1
	Talipes	1	3	0	4
	Tracheo-oesophageal fistula	0	1	0	1
	Trisomy 13	0	2	0	2
	Umbilical artery hypoplasia	0	1	0	1
Urinary tract malformation	1	0	0	1	
Vascular anomaly	0	1	0	1	
Y-linked chromosomal disorder	1	0	0	1	
Ear	Deafness	1	12	0	13
	Deafness neurosensory	0	1	0	1
	Ear discomfort	1	4	0	5
	Ear disorder	0	1	0	1
	Ear pain	1	3	0	4
	Hyperacusis	0	1	0	1
	Hypoacusis	1	1	0	2
	Meniere's disease	1	0	0	1
	Sudden hearing loss	0	1	0	1
	Tinnitus	2	14	0	16
	Vertigo	5	17	0	22
	Vestibular disorder	0	1	0	1
	Addison's disease	1	0	0	1
	Adrenal disorder	0	1	0	1
	Adrenal insufficiency	0	2	0	2
	Androgen deficiency	1	1	0	2
	Anovulatory cycle	0	2	0	2
	Autoimmune thyroiditis	1	1	0	2
	Basedow's disease	3	0	0	3
	Cushing's syndrome	1	4	0	5

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Endo	Diabetes insipidus	2	2	0	4
	Ectopic ACTH syndrome	0	1	0	1
	Endocrine disorder	1	0	0	1
	Goitre	0	8	0	8
	Hyperadrenocorticism	0	1	0	1
	Hyperparathyroidism	0	2	0	2
	Hyperprolactinaemia	0	1	0	1
	Hyperthyroidism	2	22	0	24
	Hypogonadism	0	1	0	1
	Hypopituitarism	2	3	0	5
	Hypothyroidism	1	4	0	5
	Inappropriate antidiuretic hormone secretion	0	3	0	3
	Oestrogen deficiency	1	0	0	1
	Pituitary gonadotropin hyperfunction	0	1	0	1
	Pituitary haemorrhage	2	26	0	28
	Polyglandular disorder	0	1	0	1
	Precocious puberty	0	3	0	3
	Primary hyperaldosteronism	0	2	0	2
	Secondary hypothyroidism	1	1	0	2
	Thyroid cyst	0	1	0	1
Thyroid disorder	0	2	0	2	
Thyroiditis	2	1	0	3	
Eye	Abnormal sensation in eye	0	2	0	2
	Accommodation disorder	0	3	0	3
	Amblyopia	0	3	0	3
	Asthenopia	1	0	0	1
	Blepharitis allergic	0	1	0	1
	Blepharospasm	0	4	0	4
	Blindness	2	9	0	11
	Blindness transient	0	4	0	4
	Blindness unilateral	1	3	0	4
	Cataract	3	7	1	11
	Choroidal neovascularisation	0	1	0	1
	Conjunctival haemorrhage	1	0	0	1
	Conjunctival hyperaemia	0	1	0	1
	Conjunctivitis	1	2	0	3
	Conjunctivitis allergic	0	1	0	1
	Corneal lesion	0	1	0	1
	Cystoid macular oedema	0	1	0	1
	Diplopia	2	15	0	17
	Dry eye	2	2	0	4
	Exophthalmos	0	2	0	2
	Extraocular muscle paresis	0	1	0	1
	Eye disorder	1	2	0	3
	Eye haemorrhage	0	2	0	2
	Eye inflammation	0	1	0	1
	Eye irritation	0	1	0	1
	Eye movement disorder	0	1	0	1
	Eye pain	1	4	0	5
	Eye swelling	3	2	0	5
	Eyelid disorder	0	4	0	4
	Eyelid function disorder	0	4	0	4
	Eyelid oedema	1	6	0	7
	Eyelid ptosis	1	2	0	3
	Glaucoma	1	1	0	2
	Iris hypopigmentation	0	1	0	1
	Iris neovascularisation	1	0	0	1
	Keratitis	0	2	0	2
	Lacrimal disorder	1	0	0	1
	Lacrimation increased	0	3	0	3
	Macular degeneration	2	4	0	6
	Maculopathy	0	2	0	2
Mydriasis	0	2	0	2	
Ocular hyperaemia	0	3	0	3	

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	Open angle glaucoma	0	1	0	1
	Ophthalmoplegia	0	3	0	3
	Optic atrophy	0	2	0	2
	Optic ischaemic neuropathy	1	0	0	1
	Optic nerve cupping	0	1	0	1
	Optic nerve sheath haemorrhage	0	1	0	1
	Papilloedema	1	4	0	5
	Periorbital oedema	0	1	0	1
	Photophobia	1	7	0	8
	Retinal artery occlusion	0	1	0	1
	Retinal detachment	0	3	0	3
	Retinal disorder	0	1	0	1
	Retinal dystrophy	0	1	0	1
	Retinal exudates	0	1	0	1
	Retinal haemorrhage	1	4	0	5
	Retinal infarction	0	1	0	1
	Retinal ischaemia	0	2	0	2
	Retinal vascular occlusion	0	1	0	1
	Retinal vascular thrombosis	2	1	0	3
	Retinal vein occlusion	1	10	0	11
	Scotoma	0	1	0	1
	Vision blurred	7	45	0	52
	Visual acuity reduced	7	5	0	12
	Visual impairment	9	23	0	32
	Vitreous floaters	0	2	0	2
	Vitreous loss	0	1	0	1
	Abdominal adhesions	0	1	0	1
	Abdominal discomfort	1	10	0	11
	Abdominal distension	0	33	0	33
	Abdominal hernia	2	4	0	6
	Abdominal mass	0	4	0	4
	Abdominal pain	10	90	0	100
	Abdominal pain lower	1	23	0	24
	Abdominal pain upper	3	19	0	22
	Abdominal wall haematoma	0	1	0	1
	Acute abdomen	0	2	0	2
	Aerophagia	0	1	0	1
	Aphagia	0	1	0	1
	Apthous stomatitis	0	1	0	1
	Appendix disorder	0	1	0	1
	Ascites	10	26	0	36
	Burning mouth syndrome	1	0	0	1
	Change of bowel habit	0	1	0	1
	Cheilitis	1	0	0	1
	Coeliac artery stenosis	0	1	0	1
	Coeliac disease	0	1	0	1
	Colitis	0	2	0	2
	Colitis ischaemic	0	1	0	1
	Colonic polyp	0	3	0	3
	Constipation	4	26	0	30
	Dental caries	2	1	0	3
	Diarrhoea	11	49	0	60
	Diverticulum	0	5	0	5
	Dry mouth	5	8	1	14
	Duodenitis	0	1	0	1
	Dyspepsia	2	11	0	13
	Dysphagia	3	16	0	19
	Erosive oesophagitis	0	1	0	1
	Faecal incontinence	0	7	0	7
	Faeces discoloured	0	3	0	3
	Flatulence	0	6	0	6
	Functional gastrointestinal disorder	0	2	0	2
	Gastric atony	0	1	0	1
	Gastric disorder	0	2	0	2

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Gastr	Gastric polyps	0	1	0	1
	Gastric ulcer	0	11	0	11
	Gastric ulcer haemorrhage	0	9	0	9
	Gastritis	0	10	0	10
	Gastroduodenitis	0	2	0	2
	Gastrointestinal disorder	3	6	0	9
	Gastrointestinal haemorrhage	1	12	0	13
	Gastrointestinal obstruction	0	1	0	1
	Gastrointestinal perforation	0	1	0	1
	Gastrointestinal sounds abnormal	0	1	0	1
	Gastroesophageal reflux disease	3	4	0	7
	Gingival bleeding	0	7	0	7
	Gingival disorder	0	2	0	2
	Gingival inflammation	0	1	0	1
	Haematemesis	0	5	0	5
	Haematochezia	0	2	0	2
	Haemorrhoidal haemorrhage	0	1	0	1
	Haemorrhoids	0	1	0	1
	Hiatus hernia	0	1	0	1
	Hyperchlorhydria	1	1	0	2
	Hypertrophy of tongue papillae	1	0	0	1
	Hypoaesthesia oral	0	4	0	4
	Ileus	0	5	0	5
	Impaired gastric emptying	0	2	0	2
	Inguinal hernia	0	6	0	6
	Intestinal mass	0	2	0	2
	Intestinal obstruction	0	9	0	9
	Intestinal perforation	0	1	0	1
	Intestinal stenosis	0	1	0	1
	Intra-abdominal haemorrhage	0	3	0	3
	Irritable bowel syndrome	0	2	0	2
	Large intestinal haemorrhage	0	2	0	2
	Leukoplakia oral	1	0	0	1
	Lip oedema	0	3	0	3
	Lip swelling	0	4	0	4
	Malabsorption	0	1	0	1
	Melaena	1	7	0	8
	Mesenteric artery thrombosis	0	2	0	2
	Mesenteric vein thrombosis	0	3	0	3
	Mikulicz's disease	0	1	0	1
	Mouth haemorrhage	0	1	0	1
	Mouth ulceration	1	0	0	1
	Nausea	24	154	0	178
	Odynophagia	2	0	0	2
	Oedema mouth	0	4	0	4
	Oesophageal disorder	0	2	0	2
	Oesophageal ulcer	1	1	0	2
	Oesophagitis	0	3	0	3
	Oral discharge	0	2	0	2
	Oral discomfort	0	1	0	1
	Oral disorder	0	1	0	1
	Oral pain	0	2	0	2
	Pancreatitis	1	6	0	7
	Pancreatitis acute	0	4	0	4
	Pancreatitis chronic	0	1	0	1
	Paraesthesia oral	0	4	0	4
	Peritoneal disorder	0	1	0	1
	Peritoneal haemorrhage	0	1	0	1
	Proctalgia	0	5	0	5
	Rectal haemorrhage	0	4	0	4
Rectal tenesmus	0	1	0	1	
Regurgitation	0	1	0	1	
Retching	1	1	0	2	
Retroperitoneal haematoma	0	1	0	1	

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	Salivary gland enlargement	0	1	0	1
	Salivary hypersecretion	0	1	0	1
	Small intestinal obstruction	0	1	0	1
	Stomatitis	0	8	0	8
	Subileus	1	0	0	1
	Swollen tongue	1	4	0	5
	Teeth brittle	1	1	0	2
	Tongue coated	1	0	0	1
	Tongue disorder	1	0	0	1
	Tongue haemorrhage	0	1	0	1
	Tongue oedema	2	5	0	7
	Tooth disorder	0	3	0	3
	Tooth loss	1	0	0	1
	Varices oesophageal	0	2	0	2
	Vasculitis gastrointestinal	0	1	0	1
	Vomiting	13	149	0	162
	Vomiting projectile	0	1	0	1
	Abasia	0	16	0	16
	Abscess sterile	2	4	0	6
	Adhesion	0	1	0	1
	Adverse drug reaction	0	3	0	3
	Adverse event	1	0	0	1
	Adverse reaction	0	96	0	96
	Application site discharge	0	1	0	1
	Application site eczema	0	1	0	1
	Application site erythema	0	1	0	1
	Application site haemorrhage	1	0	0	1
	Application site hypersensitivity	1	0	0	1
	Application site inflammation	1	0	0	1
	Application site irritation	1	0	0	1
	Application site necrosis	1	0	0	1
	Application site oedema	0	1	0	1
	Application site reaction	5	0	0	5
	Application site ulcer	0	1	0	1
	Asthenia	27	157	0	184
	Axillary pain	0	4	0	4
	Cardiac death	0	1	0	1
	Chest discomfort	2	16	0	18
	Chest pain	8	85	0	93
	Chills	5	26	0	31
	Chronic fatigue syndrome	1	1	0	2
	Concomitant disease progression	1	0	0	1
	Condition aggravated	10	22	0	32
	Crepitations	0	8	0	8
	Crying	0	4	0	4
	Cyst	0	8	0	8
	Death	13	64	0	77
	Denervation atrophy	1	0	0	1
	Developmental delay	0	2	0	2
	Device expulsion	0	1	0	1
	Device extrusion	0	1	0	1
	Device malfunction	0	1	0	1
	Device occlusion	1	0	0	1
	Discomfort	3	5	0	8
	Disease progression	2	22	0	24
	Drowning	0	2	0	2
	Drug effect decreased	4	5	0	9
	Drug ineffective	55	72	1	128
	Drug interaction	5	27	0	32
	Drug intolerance	2	3	0	5
	Drug resistance	0	2	0	2
	Dysplasia	0	1	0	1
	Encapsulation reaction	1	0	0	1
	Exercise tolerance decreased	0	1	0	1

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Genrl	Face oedema	3	14	0	17
	Fat necrosis	0	1	0	1
	Fat tissue increased	0	1	0	1
	Fatigue	26	139	2	167
	Feeling abnormal	1	35	0	36
	Feeling cold	0	9	0	9
	Feeling hot	3	8	0	11
	Fibrosis	1	1	0	2
	Foaming at mouth	0	1	0	1
	Foreign body reaction	0	4	0	4
	Gait disturbance	9	65	0	74
	General physical health deterioration	6	22	0	28
	General symptom	0	1	0	1
	Generalised oedema	1	12	0	13
	Granuloma	4	13	0	17
	Hernia	0	2	0	2
	Hyperthermia	0	1	0	1
	Hypertrophy	0	1	0	1
	Hypothermia	0	4	0	4
	Ill-defined disorder	0	4	0	4
	Impaired healing	1	4	0	5
	Implant site erythema	0	1	0	1
	Implant site haemorrhage	0	1	0	1
	Implant site reaction	3	0	0	3
	Induration	3	5	0	8
	Inflammation	3	12	0	15
	Influenza like illness	3	12	0	15
	Injected limb mobility decreased	1	2	0	3
	Injection site abscess sterile	11	20	0	31
	Injection site anaesthesia	0	1	0	1
	Injection site atrophy	0	2	0	2
	Injection site cyst	1	3	0	4
	Injection site discharge	0	4	0	4
	Injection site discolouration	0	1	0	1
	Injection site discomfort	0	3	0	3
	Injection site erosion	0	1	0	1
	Injection site erythema	28	128	1	157
	Injection site exfoliation	0	2	0	2
	Injection site extravasation	4	1	0	5
	Injection site granuloma	12	28	0	40
	Injection site haematoma	12	5	0	17
	Injection site haemorrhage	0	14	0	14
	Injection site hypersensitivity	2	1	0	3
	Injection site induration	22	152	0	174
	Injection site inflammation	16	9	0	25
	Injection site irritation	2	2	0	4
	Injection site mass	10	26	0	36
	Injection site movement impairment	0	1	0	1
	Injection site necrosis	10	21	0	31
	Injection site nodule	20	14	0	34
	Injection site oedema	4	3	0	7
	Injection site pain	23	107	0	130
Injection site pruritus	0	16	0	16	
Injection site rash	1	10	0	11	
Injection site reaction	30	57	0	87	
Injection site scar	0	3	0	3	
Injection site swelling	21	83	0	104	
Injection site ulcer	8	48	0	56	
Injection site vesicles	2	1	0	3	
Injection site warmth	3	15	0	18	
Irritability	1	23	0	24	
Lipogranuloma	0	1	0	1	
Local reaction	4	2	0	6	
Local swelling	0	5	0	5	

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	Localised oedema	0	1	0	1
	Malaise	18	90	0	108
	Mass	1	2	0	3
	Meteoropathy	1	0	0	1
	Mucosal inflammation	0	1	0	1
	Multi-organ failure	1	8	0	9
	Necrosis	2	3	0	5
	No therapeutic response	6	1	0	7
	Nodule	0	6	0	6
	Non-cardiac chest pain	0	1	0	1
	Oedema	8	43	0	51
	Oedema due to hepatic disease	0	1	0	1
	Oedema peripheral	22	124	0	146
	Pain	18	91	0	109
	Paradoxical drug reaction	2	0	0	2
	Performance status decreased	1	0	0	1
	Polyp	0	1	0	1
	Product quality issue	0	3	0	3
	Product substitution issue	1	0	0	1
	Pyrexia	25	189	1	215
	Sensation of foreign body	0	1	0	1
	Sensation of pressure	0	1	0	1
	Spinal pain	0	3	0	3
	Sudden death	1	6	0	7
	Swelling	1	3	0	4
	Systemic inflammatory response syndrome	0	2	0	2
	Temperature intolerance	1	1	0	2
	Terminal state	3	0	0	3
	Therapeutic response decreased	4	0	0	4
	Thirst	1	8	0	9
	Treatment failure	4	1	0	5
	Unevaluable event	0	17	0	17
	Vaccination site swelling	0	1	0	1
	Vessel puncture site haematoma	0	2	0	2
Hepat	Acute hepatic failure	0	3	0	3
	Bile duct stenosis	0	1	0	1
	Cholangitis	1	0	0	1
	Cholecystitis	0	6	0	6
	Cholecystitis acute	0	1	0	1
	Cholelithiasis	0	9	0	9
	Cholestasis	5	12	0	17
	Drug-induced liver injury	1	18	0	19
	Gallbladder disorder	0	3	0	3
	Hepatic atrophy	0	1	0	1
	Hepatic cirrhosis	4	2	0	6
	Hepatic cyst	0	1	0	1
	Hepatic failure	4	5	0	9
	Hepatic function abnormal	1	135	0	136
	Hepatic ischaemia	0	1	0	1
	Hepatic lesion	0	2	0	2
	Hepatic mass	1	1	0	2
	Hepatic necrosis	0	1	0	1
	Hepatic steatosis	1	4	0	5
	Hepatic vein occlusion	0	1	0	1
	Hepatitis	6	10	1	17
	Hepatitis acute	0	7	0	7
	Hepatitis cholestatic	1	0	0	1
	Hepatitis chronic active	1	0	0	1
	Hepatitis fulminant	1	3	0	4
	Hepatocellular injury	4	2	0	6
	Hepatomegaly	2	2	0	4
	Hepatotoxicity	1	1	0	2
	Hyperbilirubinaemia	3	3	1	7
	Jaundice	8	51	0	59

Reaction SOC	Reaction PT	Leuprorelin			
		European Economic Area	Non European Economic Area	Not Specified	Total
	Jaundice cholestatic	0	2	0	2
	Liver disorder	2	61	0	63
	Non-alcoholic steatohepatitis	1	5	0	6
	Portal hypertension	1	0	0	1
	Portal vein thrombosis	0	2	0	2
	Venoocclusive liver disease	0	1	0	1
Immun	Allergy to metals	0	1	0	1
	Anaphylactic reaction	9	31	0	40
	Anaphylactic shock	2	15	0	17
	Anaphylactoid reaction	2	16	0	18
	Anti-neutrophil cytoplasmic antibody positive vasculitis	1	0	0	1
	Decreased immune responsiveness	0	1	0	1
	Drug hypersensitivity	0	2	0	2
	Hypersensitivity	14	44	0	58
	Immune system disorder	0	2	0	2
	Kidney transplant rejection	0	2	0	2
	Multiple chemical sensitivity	0	1	0	1
	Seasonal allergy	0	2	0	2
	Serum sickness	0	2	0	2
	Transplant rejection	0	1	0	1
Type IV hypersensitivity reaction	2	1	0	3	
	Abdominal abscess	3	1	0	4
	Abdominal infection	0	1	0	1
	Abdominal wall abscess	1	0	0	1
	Abscess	10	8	0	18
	Abscess intestinal	0	1	0	1
	Abscess limb	0	1	0	1
	Abscess neck	0	1	0	1
	Abscess rupture	0	1	0	1
	Abscess soft tissue	1	0	0	1
	Alpha haemolytic streptococcal infection	0	1	0	1
	Appendicitis	0	2	0	2
	Application site cellulitis	0	1	0	1
	Application site infection	0	1	0	1
	Arthritis bacterial	0	1	0	1
	Atypical mycobacterial infection	1	1	0	2
	Atypical pneumonia	0	2	0	2
	Bacterial infection	0	4	0	4
	Biliary sepsis	0	1	0	1
	Breast abscess	0	1	0	1
	Bronchiolitis	0	3	0	3
	Bronchitis	0	4	0	4
	Bronchopulmonary aspergillosis	0	1	0	1
	Candidiasis	0	3	0	3
	Cellulitis	0	12	0	12
	Chorioamnionitis	1	0	0	1
	Chronic sinusitis	0	2	0	2
	Clostridial infection	0	4	0	4
	Clostridium difficile sepsis	0	2	0	2
	Coccidioidomycosis	0	1	0	1
	Cystitis	1	6	0	7
	Device related infection	0	1	0	1
	Dysentery	0	2	0	2
	Ear infection	1	0	0	1
	Empyema	0	2	0	2
	Endocarditis	1	0	0	1
	Endophthalmitis	0	1	0	1
	Enterococcal sepsis	0	1	0	1
	Erysipelas	1	0	0	1
	Escherichia infection	0	1	0	1
	Fungaemia	1	1	0	2
	Fungal infection	0	3	0	3
	Gastroenteritis	0	10	0	10

Reaction SOC	Reaction PT	Leuprorelin			
		European Economic Area	Non European Economic Area	Not Specified	Total
Infec	Gingivitis	2	2	0	4
	H1N1 influenza	1	0	0	1
	Helicobacter infection	0	1	0	1
	Hepatic infection	0	1	0	1
	Hepatitis B	0	2	0	2
	Herpes virus infection	0	5	0	5
	Herpes zoster	0	5	0	5
	Implant site infection	0	1	0	1
	Infection	4	14	0	18
	Influenza	1	13	0	14
	Injection site abscess	84	182	1	267
	Injection site cellulitis	1	12	0	13
	Injection site infection	8	11	0	19
	Injection site pustule	1	2	0	3
	Kidney infection	0	2	0	2
	Klebsiella infection	1	2	0	3
	Labyrinthitis	1	1	0	2
	Liver abscess	0	3	0	3
	Lung infection	0	1	0	1
	Lung infection pseudomonal	0	1	0	1
	Meningitis	0	1	0	1
	Muscle abscess	1	1	0	2
	Mycobacterial infection	0	2	0	2
	Myelitis	1	3	0	4
	Nasopharyngitis	0	3	0	3
	Necrotising fasciitis	1	0	0	1
	Neisseria infection	0	1	0	1
	Neonatal pneumonia	0	1	0	1
	Onychomycosis	0	2	0	2
	Oral candidiasis	0	1	0	1
	Oral herpes	1	0	0	1
	Osteomyelitis	0	2	0	2
	Pelvic abscess	0	3	0	3
	Pelvic inflammatory disease	0	2	0	2
	Periodontitis	0	1	0	1
	Peritonitis	0	2	0	2
	Peritonitis bacterial	0	1	0	1
	Pharyngitis	1	4	0	5
	Pneumonia	4	96	0	100
	Pneumonia bacterial	0	2	0	2
	Post procedural infection	0	1	0	1
	Post viral fatigue syndrome	1	0	0	1
	Postoperative wound infection	0	1	0	1
	Pseudomonas infection	0	2	0	2
	Pulmonary sepsis	1	0	0	1
	Puncture site infection	0	2	0	2
	Purulence	2	1	0	3
	Purulent discharge	2	5	0	7
	Pyelonephritis	0	9	0	9
	Rash pustular	1	4	0	5
	Respiratory tract infection	0	2	0	2
	Rhinitis	2	1	0	3
Rhinoscleroma	0	2	0	2	
Scrotal abscess	0	2	0	2	
Sepsis	4	12	0	16	
Septic shock	1	6	0	7	
Sinusitis	0	5	0	5	
Skin bacterial infection	0	1	0	1	
Skin infection	1	0	0	1	
Staphylococcal abscess	1	2	0	3	
Staphylococcal bacteraemia	0	1	0	1	
Staphylococcal infection	1	5	0	6	
Subcutaneous abscess	1	2	0	3	
Tooth abscess	0	2	0	2	

Reaction SOC	Reaction PT	Leuprorelin			
		European Economic Area	Non European Economic Area	Not Specified	Total
	Tuberculosis	0	1	0	1
	Upper respiratory tract infection	0	1	0	1
	Urinary tract infection	4	39	0	43
	Vaginal infection	0	2	0	2
	Vaginitis bacterial	0	1	0	1
	Varicella	0	1	0	1
	Viral infection	0	3	0	3
	Viral pharyngitis	0	1	0	1
	Viral upper respiratory tract infection	0	1	0	1
	Wound infection	0	3	0	3
Inj&P	Accidental overdose	2	1	0	3
	Animal bite	0	2	0	2
	Ankle fracture	0	2	0	2
	Arthropod bite	0	1	0	1
	Bladder injury	0	3	0	3
	Cartilage injury	0	1	0	1
	Cervical vertebral fracture	0	2	0	2
	Clavicle fracture	0	2	0	2
	Compression fracture	0	7	0	7
	Concussion	0	1	0	1
	Contusion	2	15	0	17
	Dislocation of vertebra	0	5	0	5
	Drug administered at inappropriate site	0	1	0	1
	Drug administration error	2	3	0	5
	Drug dispensing error	0	2	0	2
	Eschar	2	0	0	2
	Excoriation	0	2	0	2
	Expired drug administered	0	1	0	1
	Fall	5	81	0	86
	Femoral neck fracture	0	2	0	2
	Femur fracture	4	6	0	10
	Foetal exposure during pregnancy	0	8	0	8
	Foreign body	0	2	0	2
	Fracture	1	2	0	3
	Gun shot wound	0	1	0	1
	Head injury	0	4	0	4
	Heat stroke	0	1	0	1
	Hip fracture	0	18	0	18
	Inappropriate schedule of drug administration	1	1	0	2
	Incision site erythema	0	1	0	1
	Incorrect dose administered	1	3	0	4
	Incorrect drug administration duration	1	1	0	2
	Incorrect drug dosage form administered	0	1	0	1
	Incorrect route of drug administration	3	5	0	8
	Injury	0	11	0	11
	Jaw fracture	0	2	0	2
	Joint dislocation	1	2	0	3
	Joint injury	0	2	0	2
	Laceration	0	2	0	2
	Ligament sprain	1	0	0	1
	Limb injury	0	3	0	3
	Lower limb fracture	0	6	0	6
	Lumbar vertebral fracture	1	2	0	3
	Maternal exposure during pregnancy	0	3	0	3
	Maternal exposure timing unspecified	0	1	0	1
	Medication error	3	6	0	9
	Meniscus lesion	0	1	0	1
Multiple fractures	0	1	0	1	
Muscle injury	0	1	0	1	
Nerve injury	1	3	0	4	
Open wound	0	1	0	1	
Optic nerve injury	1	0	0	1	
Overdose	1	3	0	4	
Patella fracture	1	0	0	1	

Reaction SOC	Reaction PT	Leuprorelin			
		European Economic Area	Non European Economic Area	Not Specified	Total
	Pelvic fracture	0	2	0	2
	Poisoning	1	0	0	1
	Post procedural complication	0	1	0	1
	Post procedural haemorrhage	0	1	0	1
	Post-traumatic neck syndrome	1	0	0	1
	Procedural complication	0	6	0	6
	Procedural haemorrhage	0	1	0	1
	Procedural pain	0	2	0	2
	Radiation pneumonitis	0	1	0	1
	Radiation skin injury	0	1	0	1
	Radius fracture	0	1	0	1
	Recall phenomenon	0	1	0	1
	Rib fracture	0	8	0	8
	Road traffic accident	0	6	0	6
	Sciatic nerve injury	1	0	0	1
	Scratch	0	1	0	1
	Skull fracture	0	2	0	2
	Spinal compression fracture	1	7	0	8
	Spinal fracture	1	5	0	6
	Subcutaneous haematoma	0	1	0	1
	Subdural haematoma	0	8	0	8
	Suture related complication	0	2	0	2
	Suture rupture	0	2	0	2
	Thoracic vertebral fracture	1	0	0	1
	Tibia fracture	0	1	0	1
	Tooth fracture	0	2	0	2
	Toxicity to various agents	0	6	0	6
	Underdose	0	1	0	1
	Upper limb fracture	0	4	0	4
	Uterine perforation	0	1	0	1
	Wound	2	6	0	8
	Wound dehiscence	0	1	0	1
	Wound necrosis	0	2	0	2
	Wound secretion	3	0	0	3
	Wrist fracture	1	4	0	5
	Wrong technique in drug usage process	2	2	0	4
	5-hydroxyindolacetic acid increased	0	1	0	1
	Alanine aminotransferase increased	7	93	0	100
	Alpha 1 foetoprotein normal	1	0	0	1
	Amylase increased	0	4	0	4
	Antibody test abnormal	0	2	0	2
	Antinuclear antibody increased	0	1	0	1
	Antinuclear antibody positive	0	2	0	2
	Antithrombin III decreased	0	1	0	1
	Aspartate aminotransferase abnormal	0	1	0	1
	Aspartate aminotransferase increased	7	99	0	106
	Bacterial test positive	0	1	0	1
	Bilirubin conjugated increased	0	1	0	1
	Bleeding time prolonged	0	5	0	5
	Blood albumin decreased	0	1	0	1
	Blood aldosterone increased	0	1	0	1
	Blood alkaline phosphatase decreased	0	1	0	1
	Blood alkaline phosphatase increased	5	48	0	53
	Blood bicarbonate decreased	1	0	0	1
	Blood bicarbonate increased	0	1	0	1
	Blood bilirubin increased	1	32	0	33
	Blood calcium increased	0	1	0	1
	Blood chloride decreased	1	0	0	1
	Blood chloride increased	0	1	0	1
	Blood cholesterol increased	2	11	0	13
	Blood cholinesterase decreased	0	1	0	1
	Blood corticotrophin increased	0	2	0	2
	Blood cortisol abnormal	0	1	0	1
	Blood cortisol increased	0	4	0	4

Reaction SOC	Reaction PT	Leuprorelin			
		European Economic Area	Non European Economic Area	Not Specified	Total
	Blood creatine increased	1	2	0	3
	Blood creatine phosphokinase abnormal	0	1	0	1
	Blood creatine phosphokinase increased	4	23	0	27
	Blood creatine phosphokinase MB	1	0	0	1
	Blood creatinine increased	6	19	0	25
	Blood culture positive	0	1	0	1
	Blood follicle stimulating hormone increased	1	0	0	1
	Blood glucose abnormal	1	0	0	1
	Blood glucose decreased	1	4	0	5
	Blood glucose increased	3	34	0	37
	Blood gonadotrophin increased	0	1	0	1
	Blood growth hormone increased	0	3	0	3
	Blood immunoglobulin G increased	0	1	0	1
	Blood iron increased	0	1	0	1
	Blood ketone body increased	0	2	0	2
	Blood lactate dehydrogenase increased	4	36	0	40
	Blood oestrogen decreased	1	2	0	3
	Blood oestrogen increased	0	3	0	3
	Blood osmolarity decreased	0	1	0	1
	Blood parathyroid hormone increased	0	3	0	3
	Blood potassium decreased	0	5	0	5
	Blood potassium increased	1	1	0	2
	Blood pressure abnormal	1	0	0	1
	Blood pressure decreased	3	19	0	22
	Blood pressure diastolic increased	0	2	0	2
	Blood pressure increased	5	45	0	50
	Blood pressure systolic increased	1	0	0	1
	Blood prolactin abnormal	0	1	0	1
	Blood prolactin increased	0	2	0	2
	Blood sodium abnormal	0	1	0	1
	Blood sodium decreased	2	0	0	2
	Blood sodium increased	0	1	0	1
	Blood test abnormal	0	1	0	1
	Blood testosterone abnormal	2	2	0	4
	Blood testosterone decreased	0	5	0	5
	Blood testosterone increased	10	13	0	23
	Blood testosterone normal	2	0	0	2
	Blood thromboplastin decreased	0	1	0	1
	Blood triglycerides increased	0	5	0	5
	Blood urea increased	0	12	0	12
	Blood uric acid increased	0	1	0	1
	Blood urine present	0	6	0	6
	Body height decreased	0	4	0	4
	Body temperature increased	1	4	0	5
	Bone density decreased	2	8	0	10
	Bone scan abnormal	0	2	0	2
	Brain natriuretic peptide increased	1	0	0	1
	Breath sounds abnormal	0	1	0	1
	C-reactive protein increased	1	26	0	27
	Carcinoembryonic antigen increased	0	1	0	1
	Cardiac enzymes increased	0	1	0	1
	Cardiac murmur	2	2	0	4
	Cardiac output decreased	0	3	0	3
	Cell marker increased	0	4	0	4
	Central venous pressure decreased	0	1	0	1
	Chest X-ray abnormal	0	22	0	22
	Coagulation time shortened	1	0	0	1
	Complement factor decreased	0	1	0	1
	Computerised tomogram abnormal	1	4	0	5
	CSF pressure increased	0	1	0	1
	Culture urine positive	1	0	0	1
	Drug level increased	0	2	0	2
	Drug specific antibody absent	0	1	0	1
	Echocardiogram abnormal	0	2	0	2

Reaction SOC	Reaction PT	Leuprorelin			
		European Economic Area	Non European Economic Area	Not Specified	Total
Inv	Ejection fraction decreased	0	2	0	2
	Electrocardiogram abnormal	1	5	0	6
	Electrocardiogram normal	0	1	0	1
	Electrocardiogram QT prolonged	0	1	0	1
	Electrocardiogram ST segment depression	0	1	0	1
	Electrocardiogram ST segment elevation	0	3	0	3
	Electrocardiogram ST-T change	0	1	0	1
	Electrocardiogram T wave abnormal	0	1	0	1
	Endoscopy abnormal	1	0	0	1
	Eosinophil count increased	0	7	0	7
	Fibrin D dimer increased	1	1	0	2
	Fibrin degradation products increased	0	1	0	1
	Fibrinolysis increased	0	1	0	1
	Foetal heart rate abnormal	0	1	0	1
	Foetal heart rate decreased	0	1	0	1
	Foetal monitoring	1	0	0	1
	Gamma-glutamyltransferase increased	6	45	0	51
	Glucocorticoids increased	0	1	0	1
	Glucose tolerance decreased	0	5	0	5
	Glucose urine present	0	5	0	5
	Glycosylated haemoglobin increased	3	11	0	14
	Grip strength decreased	0	2	0	2
	Haematocrit decreased	0	11	0	11
	Haematocrit increased	0	2	0	2
	Haemoglobin abnormal	0	2	0	2
	Haemoglobin decreased	1	34	0	35
	Haemoglobin increased	0	3	0	3
	Heart rate decreased	1	6	0	7
	Heart rate increased	0	15	0	15
	Heart rate irregular	1	10	0	11
	Hepatic enzyme increased	7	17	0	24
	High density lipoprotein decreased	0	2	0	2
	Histology abnormal	0	1	0	1
	Hormone level abnormal	2	6	0	8
	Human chorionic gonadotropin decreased	0	1	0	1
	Immunoglobulins abnormal	0	1	0	1
	Immunoglobulins increased	0	1	0	1
	Immunosuppressant drug level increased	0	1	0	1
	International normalised ratio decreased	2	0	0	2
	International normalised ratio increased	1	5	0	6
	Laboratory test abnormal	0	9	0	9
	Left ventricular end-diastolic pressure increased	0	1	0	1
	Leucine aminopeptidase increased	0	1	0	1
	Lipase increased	0	1	0	1
	Liver function test abnormal	3	13	0	16
	Liver scan abnormal	1	3	0	4
	Low density lipoprotein increased	1	2	0	3
	Lymphocyte count increased	0	1	0	1
	Nerve conduction studies abnormal	0	2	0	2
	Neutrophil count decreased	0	2	0	2
	Neutrophil count increased	0	1	0	1
Nuclear magnetic resonance imaging abnormal	0	1	0	1	
Occult blood positive	0	4	0	4	
Oestradiol abnormal	0	1	0	1	
Oestradiol decreased	0	3	0	3	
Oestradiol increased	2	5	0	7	
Oxygen saturation decreased	1	11	0	12	
Pancreatic enzymes abnormal	0	1	0	1	
Pancreatic enzymes increased	2	0	0	2	
Platelet aggregation decreased	0	1	0	1	
Platelet count abnormal	0	2	0	2	
Platelet count decreased	0	52	0	52	
PO2 decreased	0	1	0	1	
Prostatic specific antigen abnormal	0	2	0	2	

Reaction SOC	Reaction PT	Leuprorelin			
		European Economic Area	Non European Economic Area	Not Specified	Total
	Prostatic specific antigen decreased	0	3	0	3
	Prostatic specific antigen increased	35	67	0	102
	Protein total decreased	0	1	0	1
	Prothrombin level abnormal	0	2	0	2
	Prothrombin level decreased	0	2	0	2
	Prothrombin level increased	0	1	0	1
	Prothrombin time abnormal	0	4	0	4
	Prothrombin time prolonged	2	5	0	7
	Prothrombin time ratio decreased	0	2	0	2
	Pulse abnormal	0	1	0	1
	Pulse absent	0	2	0	2
	Quality of life decreased	1	1	0	2
	Red blood cell count decreased	0	14	0	14
	Red blood cell sedimentation rate increased	0	3	0	3
	Renal scan abnormal	0	1	0	1
	Respiratory rate increased	0	1	0	1
	Reticulocyte count decreased	0	2	0	2
	Scan gallium abnormal	0	1	0	1
	Serum ferritin increased	1	0	0	1
	Spleen scan abnormal	1	0	0	1
	T-lymphocyte count increased	0	1	0	1
	Thrombin time prolonged	1	0	0	1
	Thyroid function test abnormal	0	3	0	3
	Transaminases increased	7	0	0	7
	Tumour marker increased	0	3	0	3
	Ultrasound uterus abnormal	0	1	0	1
	Urine analysis abnormal	0	1	0	1
	Urine calcium increased	0	3	0	3
	Urine ketone body present	0	1	0	1
	Urine output	0	2	0	2
	Urine output decreased	0	5	0	5
	Urine output increased	0	1	0	1
	Vital capacity decreased	0	1	0	1
	Vitamin B12 decreased	1	1	0	2
	Vitamin D decreased	0	1	0	1
	Waist circumference increased	0	1	0	1
	Weight decreased	15	71	0	86
	Weight increased	3	65	2	70
	White blood cell count decreased	1	17	0	18
	White blood cell count increased	0	21	0	21
	X-ray abnormal	0	3	0	3
	Acidosis	0	2	0	2
	Alkalosis	0	1	0	1
	Appetite disorder	1	1	0	2
	Body fat disorder	0	3	0	3
	Cachexia	0	2	0	2
	Central obesity	1	0	0	1
	Decreased appetite	6	143	0	149
	Dehydration	2	54	0	56
	Diabetes mellitus	5	76	0	81
	Diabetes mellitus inadequate control	0	3	0	3
	Diabetes with hyperosmolarity	0	2	0	2
	Diabetic ketoacidosis	0	1	0	1
	Dyslipidaemia	0	1	0	1
	Electrolyte imbalance	0	1	0	1
	Fluid retention	0	11	0	11
	Folate deficiency	0	4	0	4
	Glucose tolerance impaired	1	6	0	7
	Gout	0	5	0	5
	Hypercalcaemia	0	2	0	2
	Hypercholesterolaemia	1	6	0	7
	Hyperglycaemia	4	38	0	42
	Hyperglycaemic hyperosmolar nonketotic syndrome	0	1	0	1
	Hyperhomocysteinaemia	0	1	0	1

Reaction SOC	Reaction PT	Leuprorelin			
		European Economic Area	Non European Economic Area	Not Specified	Total
Metab	Hyperkalaemia	0	4	0	4
	Hyperlipidaemia	0	7	0	7
	Hypernatraemia	0	3	0	3
	Hypertriglyceridaemia	0	1	0	1
	Hyperuricaemia	1	3	0	4
	Hypoalbuminaemia	0	3	0	3
	Hypocalcaemia	2	2	0	4
	Hypochloraemia	0	1	0	1
	Hypoglycaemia	1	6	0	7
	Hypokalaemia	1	8	0	9
	Hyponatraemia	2	10	0	12
	Hypophagia	0	18	0	18
	Hypoproteinaemia	0	5	0	5
	Increased appetite	0	2	0	2
	Insulin resistance	0	1	0	1
	Iron deficiency	0	4	0	4
	Ketoacidosis	0	2	0	2
	Ketosis	0	4	0	4
	Malnutrition	1	0	0	1
	Marasmus	0	2	0	2
	Metabolic acidosis	1	3	0	4
	Metabolic disorder	1	0	0	1
	Metabolic syndrome	2	0	0	2
	Obesity	0	1	0	1
	Overweight	0	1	0	1
	Polydipsia	0	3	0	3
	Type 1 diabetes mellitus	2	4	0	6
	Type 2 diabetes mellitus	2	7	1	10
	Vitamin B12 deficiency	0	2	0	2
	Vitamin D deficiency	0	2	0	2
Weight fluctuation	0	1	0	1	
	Amyotrophy	1	0	0	1
	Arthralgia	20	125	2	147
	Arthritis	2	15	0	17
	Arthropathy	1	5	0	6
	Back disorder	0	1	0	1
	Back pain	5	73	0	78
	Bone cyst	0	1	0	1
	Bone disorder	0	11	0	11
	Bone lesion	0	7	0	7
	Bone loss	0	1	0	1
	Bone pain	14	63	0	77
	Chondropathy	0	2	0	2
	Clubbing	0	1	0	1
	Coccydynia	0	1	0	1
	Collagen disorder	0	1	0	1
	Costochondritis	0	1	0	1
	Delayed closure of cranial sutures	0	1	0	1
	Epiphysiolysis	1	11	0	12
	Exposed bone in jaw	0	1	0	1
	Fibromyalgia	2	12	0	14
	Finger deformity	0	1	0	1
	Fistula	0	3	0	3
	Flank pain	0	3	0	3
	Groin pain	0	6	0	6
	Inguinal mass	0	2	0	2
	Intervertebral disc degeneration	1	4	0	5
	Intervertebral disc protrusion	3	5	0	8
	Jaw disorder	0	4	0	4
	Joint contracture	0	1	0	1
	Joint crepitation	1	1	0	2
	Joint destruction	0	1	0	1
	Joint effusion	0	1	0	1
	Joint range of motion decreased	0	7	0	7

Reaction SOC	Reaction PT	Leuprorelin			
		European Economic Area	Non European Economic Area	Not Specified	Total
Musc	Joint stiffness	2	12	0	14
	Joint swelling	6	9	0	15
	Kyphoscoliosis	0	1	0	1
	Kyphosis	0	1	0	1
	Limb deformity	1	0	0	1
	Limb discomfort	0	3	0	3
	Lumbar spinal stenosis	0	1	0	1
	Lupus-like syndrome	0	2	0	2
	Mastication disorder	1	0	0	1
	Mobility decreased	3	13	0	16
	Muscle atrophy	3	14	0	17
	Muscle contracture	0	4	0	4
	Muscle disorder	1	1	0	2
	Muscle haemorrhage	0	1	0	1
	Muscle mass	0	2	0	2
	Muscle necrosis	0	4	0	4
	Muscle rigidity	0	2	0	2
	Muscle spasms	3	33	0	36
	Muscle tightness	0	1	0	1
	Muscle twitching	1	4	0	5
	Muscular weakness	15	78	1	94
	Musculoskeletal chest pain	1	2	0	3
	Musculoskeletal discomfort	1	0	0	1
	Musculoskeletal disorder	0	4	0	4
	Musculoskeletal pain	4	20	0	24
	Musculoskeletal stiffness	2	32	0	34
	Myalgia	18	78	1	97
	Myofascial pain syndrome	0	1	0	1
	Myopathy	6	5	0	11
	Myopathy toxic	0	1	0	1
	Myositis	2	6	0	8
	Neck pain	5	15	0	20
	Osteitis	0	2	0	2
	Osteoarthritis	1	10	0	11
	Osteolysis	0	1	0	1
	Osteomalacia	0	1	0	1
	Osteonecrosis	0	4	0	4
	Osteonecrosis of jaw	0	4	0	4
	Osteopenia	2	6	0	8
	Osteoporosis	5	34	0	39
	Osteoporotic fracture	0	2	0	2
	Pain in extremity	7	78	1	86
	Pain in jaw	1	3	0	4
	Pathological fracture	1	6	0	7
	Polyarthritis	1	3	0	4
	Polychondritis	0	1	0	1
	Polymyalgia rheumatica	0	4	1	5
	Polymyositis	1	3	0	4
	Posture abnormal	0	1	0	1
	Primary sequestrum	0	1	0	1
	Rhabdomyolysis	1	20	0	21
Rheumatoid arthritis	0	8	0	8	
Rotator cuff syndrome	0	2	0	2	
Scleroderma	1	1	0	2	
Scoliosis	1	3	0	4	
Sensation of heaviness	1	4	0	5	
Sjogren's syndrome	0	1	0	1	
Soft tissue disorder	2	1	0	3	
Soft tissue mass	0	3	0	3	
Soft tissue necrosis	1	1	0	2	
Spinal column stenosis	0	2	0	2	
Spinal osteoarthritis	1	6	0	7	
Synovial cyst	0	1	0	1	
Synovitis	0	1	0	1	

Reaction SOC	Reaction PT	Leuprorelin			
		European Economic Area	Non European Economic Area	Not Specified	Total
	Systemic lupus erythematosus	3	11	0	14
	Tendinous contracture	0	1	0	1
	Tendon disorder	1	1	0	2
	Tendon pain	1	0	0	1
	Tendonitis	2	1	0	3
	Tenosynovitis	0	8	0	8
	Torticollis	0	1	0	1
	Trigger finger	0	1	0	1
	Weight bearing difficulty	0	1	0	1
	Abdominal neoplasm	0	1	0	1
	Acute lymphocytic leukaemia	1	0	0	1
	Acute myeloid leukaemia	0	5	0	5
	Adenocarcinoma	0	2	0	2
	Adenoma benign	0	1	0	1
	Adrenal adenoma	0	2	0	2
	Astrocytoma	0	1	0	1
	Basal cell carcinoma	1	3	0	4
	Benign biliary neoplasm	0	1	0	1
	Benign breast neoplasm	0	1	0	1
	Benign ovarian tumour	0	1	0	1
	Benign uterine neoplasm	0	1	0	1
	Bile duct cancer	0	3	0	3
	Bladder adenocarcinoma stage unspecified	0	1	0	1
	Bladder cancer	1	5	0	6
	Bladder neoplasm	0	1	0	1
	Bone cancer metastatic	0	2	0	2
	Bone neoplasm malignant	0	3	0	3
	Bowen's disease	0	1	0	1
	Brain cancer metastatic	0	1	0	1
	Brain neoplasm	0	6	0	6
	Brain neoplasm benign	0	1	0	1
	Brain neoplasm malignant	0	1	0	1
	Breast cancer	1	10	0	11
	Breast cancer male	0	8	0	8
	Cancer pain	0	4	0	4
	Colon adenoma	0	1	0	1
	Colon cancer	0	3	0	3
	Colon cancer metastatic	0	2	0	2
	Colon cancer recurrent	0	1	0	1
	Degeneration of uterine leiomyoma	0	1	0	1
	Endometrial cancer	0	5	0	5
	Endometrial sarcoma	0	1	0	1
	Focal nodular hyperplasia	1	2	0	3
	Gastric cancer	1	10	0	11
	Gastrointestinal carcinoma	0	5	0	5
	Haemangioma	0	1	0	1
	Hepatic cancer metastatic	0	2	0	2
	Hepatic neoplasm	0	1	0	1
	Hepatic neoplasm malignant	1	4	0	5
	Histiocytosis haematophagic	0	1	0	1
	Laryngeal cancer	0	1	0	1
	Lentigo maligna	0	1	0	1
	Leukaemia	0	3	0	3
	Lung carcinoma cell type unspecified recurrent	0	2	0	2
	Lung neoplasm malignant	0	17	0	17
	Lymphoma	0	4	0	4
	Malignant ascites	0	1	0	1
	Malignant melanoma	0	5	0	5
	Malignant neoplasm progression	1	8	0	9
	Malignant pleural effusion	0	2	0	2
	Melanocytic naevus	0	3	0	3
	Meningioma	1	0	0	1
	Metastases to adrenals	0	1	0	1
	Metastases to bone	1	30	0	31

Reaction SOC	Reaction PT	Leuprorelin			
		European Economic Area	Non European Economic Area	Not Specified	Total
Neopl	Metastases to central nervous system	1	4	0	5
	Metastases to liver	1	12	0	13
	Metastases to lung	0	8	0	8
	Metastases to lymph nodes	1	4	0	5
	Metastases to oesophagus	0	1	0	1
	Metastases to peritoneum	0	1	0	1
	Metastases to spine	0	3	0	3
	Metastasis	1	3	0	4
	Metastatic neoplasm	1	4	0	5
	Monoclonal gammopathy	0	1	0	1
	Multiple myeloma	0	1	0	1
	Myelodysplastic syndrome	2	12	0	14
	Myeloid leukaemia	0	1	0	1
	Myeloproliferative disorder	0	2	0	2
	Neoplasm	2	12	0	14
	Neoplasm malignant	3	10	0	13
	Neoplasm prostate	0	1	0	1
	Neuroendocrine carcinoma	0	1	0	1
	Neuroendocrine tumour	0	1	0	1
	Non-Hodgkin's lymphoma	1	1	0	2
	Oesophageal adenocarcinoma	0	1	0	1
	Oesophageal carcinoma	0	4	0	4
	Osteoma cutis	0	1	0	1
	Ovarian cancer	0	1	0	1
	Ovarian germ cell teratoma benign	0	3	0	3
	Ovarian neoplasm	0	6	0	6
	Pancreatic carcinoma	0	3	0	3
	Pancreatic neoplasm	0	2	0	2
	Papilloma	1	0	0	1
	Paraneoplastic syndrome	1	0	0	1
	Parathyroid tumour benign	0	2	0	2
	Pituitary tumour	0	4	0	4
	Pituitary tumour benign	2	10	1	13
	Prostate cancer	3	63	0	66
	Prostate cancer metastatic	3	12	0	15
	Prostate cancer recurrent	0	5	0	5
	Prostate cancer stage II	0	2	0	2
	Prostate cancer stage III	0	2	0	2
	Prostate cancer stage IV	0	1	0	1
	Recurrent cancer	0	4	0	4
	Refractory cytopenia with unilineage dysplasia	0	1	0	1
	Renal cancer metastatic	0	1	0	1
	Sarcoma	0	5	0	5
	Scrotal cancer	0	2	0	2
	Second primary malignancy	0	1	0	1
	Skin cancer	0	7	0	7
	Small cell lung cancer stage unspecified	1	1	0	2
	Spinal cord neoplasm	0	2	0	2
	Squamous cell carcinoma	0	5	0	5
	Testicular cancer metastatic	0	1	0	1
Testicular germ cell cancer	0	1	0	1	
Throat cancer	0	1	0	1	
Thyroid cancer	0	6	0	6	
Thyroid neoplasm	0	2	0	2	
Tumour flare	0	1	0	1	
Tumour rupture	0	1	0	1	
Ureteric cancer	0	1	0	1	
Uterine cancer	0	4	0	4	
Uterine leiomyoma	0	13	0	13	
Uterine leiomyosarcoma	1	0	0	1	
Uterine neoplasm	0	1	0	1	
Ageusia	1	1	0	2	
Agnosia	0	1	0	1	
Akathisia	1	0	0	1	

Reaction SOC	Reaction PT	Leuprorelin			
		European Economic Area	Non European Economic Area	Not Specified	Total
	Altered state of consciousness	0	9	0	9
	Amnesia	2	55	1	58
	Amnesic disorder	0	1	0	1
	Amyotrophic lateral sclerosis	1	0	0	1
	Anaesthesia	1	0	0	1
	Anosmia	0	1	0	1
	Aphasia	0	14	0	14
	Aphonia	0	1	0	1
	Areflexia	0	1	0	1
	Ataxia	1	2	0	3
	Autonomic nervous system imbalance	0	3	0	3
	Autonomic neuropathy	1	0	0	1
	Axonal neuropathy	0	3	0	3
	Balance disorder	4	16	1	21
	Basal ganglion degeneration	0	1	0	1
	Benign intracranial hypertension	2	6	0	8
	Brain injury	0	1	0	1
	Brain oedema	1	2	0	3
	Brain stem infarction	0	1	0	1
	Burning sensation	0	9	0	9
	Carotid artery dissection	3	1	0	4
	Carotid artery occlusion	0	1	0	1
	Carotid artery stenosis	1	2	0	3
	Carpal tunnel syndrome	4	28	0	32
	Central nervous system lesion	0	1	0	1
	Cerebellar ataxia	1	1	0	2
	Cerebellar haemorrhage	0	1	0	1
	Cerebellar infarction	0	6	0	6
	Cerebellar syndrome	3	0	0	3
	Cerebral artery embolism	0	2	1	3
	Cerebral artery thrombosis	1	0	0	1
	Cerebral atrophy	0	2	0	2
	Cerebral cyst	0	1	0	1
	Cerebral haematoma	0	1	0	1
	Cerebral haemorrhage	1	25	0	26
	Cerebral infarction	3	62	0	65
	Cerebral ischaemia	1	8	0	9
	Cerebral thrombosis	0	2	0	2
	Cerebral vasoconstriction	0	1	0	1
	Cerebrovascular accident	10	64	1	75
	Cerebrovascular disorder	1	3	0	4
	Cerebrovascular spasm	0	1	0	1
	Cervical myelopathy	0	1	0	1
	Cervicobrachial syndrome	1	1	0	2
	Clonus	0	2	0	2
	Cognitive disorder	1	9	0	10
	Coma	1	6	0	7
	Coma hepatic	0	1	0	1
	Complex partial seizures	0	4	0	4
	Convulsion	2	71	0	73
	Coordination abnormal	0	3	0	3
	Cranial nerve paralysis	0	1	0	1
	Dementia	0	13	0	13
	Dementia Alzheimer's type	0	1	0	1
	Demyelination	1	1	0	2
	Depressed level of consciousness	0	16	0	16
	Diabetic coma	0	6	0	6
	Diabetic hyperosmolar coma	0	2	0	2
	Diplegia	2	3	0	5
	Disturbance in attention	6	19	0	25
	Dizziness	14	146	1	161
	Dizziness postural	0	1	0	1
	Drooling	0	2	0	2
	Dysaesthesia	1	0	0	1

Reaction SOC	Reaction PT	Leuprorelin			
		European Economic Area	Non European Economic Area	Not Specified	Total
Nerv	Dysarthria	2	20	0	22
	Dysgeusia	2	12	0	14
	Dyskinesia	2	1	0	3
	Dyslalia	0	3	0	3
	Dysstasia	0	5	0	5
	Dystonia	2	1	0	3
	Embolic cerebral infarction	0	2	0	2
	Encephalitis	0	2	0	2
	Encephalomalacia	0	1	0	1
	Encephalopathy	2	1	0	3
	Epilepsy	1	6	0	7
	Formication	1	1	0	2
	Fumbling	1	0	0	1
	Grand mal convulsion	1	23	0	24
	Guillain-Barre syndrome	1	5	0	6
	Haemorrhage intracranial	0	2	0	2
	Haemorrhagic cerebral infarction	0	2	0	2
	Head discomfort	0	1	0	1
	Headache	24	191	1	216
	Hemiparesis	3	5	0	8
	Hemiplegia	0	15	0	15
	Hepatic encephalopathy	0	3	0	3
	Hydrocephalus	0	1	0	1
	Hyperaesthesia	1	1	0	2
	Hyperreflexia	0	1	0	1
	Hypersomnia	0	2	0	2
	Hypertensive encephalopathy	1	0	0	1
	Hypertonia	0	5	0	5
	Hypoaesthesia	6	84	0	90
	Hypogeusia	0	1	0	1
	Hypokinesia	0	2	0	2
	Hypotonia	0	2	0	2
	Hypoxic-ischaemic encephalopathy	1	0	0	1
	IIIrd nerve paralysis	0	8	0	8
	Incoherent	0	1	0	1
	Intracranial aneurysm	0	1	0	1
	Intracranial hypotension	0	2	0	2
	Intracranial pressure increased	2	2	0	4
	Intracranial venous sinus thrombosis	0	5	0	5
	Ischaemic stroke	5	4	0	9
	Lacunar infarction	0	1	0	1
	Lethargy	2	14	0	16
	Loss of consciousness	6	51	1	58
	Lower motor neurone lesion	1	0	0	1
	Memory impairment	6	22	0	28
	Mental impairment	0	3	0	3
	Metabolic encephalopathy	1	0	0	1
	Migraine	2	54	0	56
	Migraine without aura	0	1	0	1
	Monoplegia	2	4	0	6
	Motor dysfunction	0	2	0	2
Movement disorder	0	1	0	1	
Multiple sclerosis	0	3	0	3	
Multiple sclerosis relapse	0	2	0	2	
Muscle contractions involuntary	1	0	0	1	
Myasthenia gravis	0	1	0	1	
Myelitis transverse	0	1	0	1	
Myelopathy	0	2	0	2	
Myoclonus	1	2	0	3	
Nerve compression	0	2	0	2	
Nerve root lesion	0	1	0	1	
Nervous system disorder	0	3	0	3	
Neuralgia	1	6	0	7	
Neuritis	0	1	0	1	

Reaction SOC	Reaction PT	Leuprorelin			
		European Economic Area	Non European Economic Area	Not Specified	Total
	Neurological symptom	1	2	0	3
	Neuromyopathy	0	3	0	3
	Neuropathy peripheral	2	30	0	32
	Nystagmus	0	1	0	1
	Optic neuritis	2	9	0	11
	Pachymeningitis	1	0	0	1
	Paraesthesia	12	52	1	65
	Paralysis	2	15	0	17
	Paraplegia	0	2	0	2
	Paresis	2	0	0	2
	Parkinson's disease	3	1	0	4
	Parkinsonism	1	0	0	1
	Parosmia	1	4	0	5
	Peripheral motor neuropathy	0	1	0	1
	Peripheral paralysis	0	1	0	1
	Peripheral sensorimotor neuropathy	1	1	0	2
	Peripheral sensory neuropathy	0	2	0	2
	Peroneal nerve palsy	0	1	0	1
	Petit mal epilepsy	0	4	0	4
	Polyneuropathy	7	0	1	8
	Poor quality sleep	0	2	0	2
	Posterior reversible encephalopathy syndrome	0	6	0	6
	Presyncope	2	7	0	9
	Psychomotor hyperactivity	0	2	0	2
	Psychomotor skills impaired	0	1	0	1
	Quadriplegia	0	2	0	2
	Radial nerve compression	0	1	0	1
	Radial nerve palsy	0	2	0	2
	Radiculopathy	0	2	0	2
	Restless legs syndrome	1	1	0	2
	Sciatica	1	4	0	5
	Sedation	0	1	0	1
	Sensory disturbance	1	11	0	12
	Sensory loss	0	3	0	3
	Serotonin syndrome	0	1	0	1
	Somnolence	4	16	0	20
	Speech disorder	1	14	0	15
	Spinal cord compression	0	2	0	2
	Status epilepticus	0	2	0	2
	Stupor	0	2	0	2
	Subarachnoid haemorrhage	0	6	0	6
	Superior sagittal sinus thrombosis	0	1	0	1
	Syncope	10	64	0	74
	Tardive dyskinesia	0	1	0	1
	Tension headache	1	2	0	3
	Thalamic infarction	0	1	0	1
	Thrombotic cerebral infarction	0	3	0	3
	Tongue paralysis	0	1	0	1
	Transient ischaemic attack	0	15	0	15
	Tremor	1	35	0	36
	Tunnel vision	0	1	0	1
	Unresponsive to stimuli	0	2	0	2
	VIIth nerve paralysis	2	8	0	10
	Visual field defect	1	4	0	5
	Abnormal labour	0	1	0	1
	Abortion	0	5	0	5
	Abortion missed	1	9	0	10
	Abortion spontaneous	3	35	0	38
	Breech presentation	0	1	0	1
	Cervical incompetence	0	1	0	1
	Complication of pregnancy	0	5	0	5
	Eclampsia	1	0	0	1
	Ectopic pregnancy	0	2	0	2
	Foetal cardiac disorder	0	1	0	1

Reaction SOC	Reaction PT	Leuprorelin			
		European Economic Area	Non European Economic Area	Not Specified	Total
Preg	Foetal death	0	4	0	4
	Foetal disorder	0	2	0	2
	Foetal growth restriction	1	2	0	3
	Foetal hypokinesia	0	1	0	1
	Haemorrhage in pregnancy	0	2	0	2
	Low birth weight baby	1	2	0	3
	Oligohydramnios	0	4	0	4
	Placenta praevia	0	2	0	2
	Postpartum haemorrhage	0	1	0	1
	Pre-eclampsia	0	3	0	3
	Pregnancy	2	3	0	5
	Premature baby	1	5	0	6
	Premature delivery	1	0	0	1
	Premature labour	0	2	0	2
	Premature rupture of membranes	0	1	0	1
	Small for dates baby	1	0	0	1
	Stillbirth	0	1	0	1
	Twin pregnancy	0	1	0	1
	Umbilical cord abnormality	1	0	0	1
	Umbilical cord vascular disorder	1	0	0	1
Unintended pregnancy	1	0	0	1	
	Abnormal behaviour	1	12	0	13
	Abulia	0	2	0	2
	Acute psychosis	1	0	0	1
	Affect lability	0	18	0	18
	Affective disorder	1	0	0	1
	Aggression	1	10	0	11
	Agitated depression	1	0	0	1
	Agitation	1	13	0	14
	Alcohol withdrawal syndrome	1	0	0	1
	Anger	0	7	0	7
	Anhedonia	0	1	0	1
	Anxiety	8	62	1	71
	Anxiety disorder	0	2	0	2
	Apathy	0	2	0	2
	Attention deficit/hyperactivity disorder	0	2	0	2
	Bipolar disorder	0	1	0	1
	Bipolar I disorder	0	7	0	7
	Catatonia	0	2	0	2
	Communication disorder	0	2	0	2
	Completed suicide	1	8	0	9
	Confusional state	7	46	0	53
	Conversion disorder	0	8	0	8
	Decreased activity	0	2	0	2
	Deja vu	0	1	0	1
	Delirium	1	13	0	14
	Delusion	1	15	0	16
	Depressed mood	6	0	0	6
	Depression	18	138	1	157
	Depression suicidal	1	1	0	2
	Disorientation	1	22	0	23
	Distractibility	0	1	0	1
	Drug abuse	0	1	0	1
	Eating disorder	0	3	0	3
	Elevated mood	0	2	0	2
	Emotional disorder	1	2	0	3
	Emotional distress	1	2	0	3
	Expressive language disorder	0	1	0	1
	Fear	0	1	0	1
	Feeling of despair	0	3	0	3
	Hallucination	2	20	0	22
	Hallucination, auditory	0	4	0	4
	Hallucination, visual	1	4	0	5
	Homicidal ideation	0	2	0	2

Reaction SOC	Reaction PT	Leuprorelin			
		European Economic Area	Non European Economic Area	Not Specified	Total
Psych	Hostility	0	2	0	2
	Illusion	1	1	0	2
	Impaired self-care	1	0	0	1
	Impatience	1	2	0	3
	Impulsive behaviour	1	0	0	1
	Insomnia	9	98	0	107
	Intentional self-injury	0	2	0	2
	Libido decreased	1	13	0	14
	Logorrhoea	0	1	0	1
	Loss of libido	5	9	0	14
	Major depression	0	1	0	1
	Mania	0	15	0	15
	Mental disorder	1	2	0	3
	Mental status changes	2	2	0	4
	Mood altered	2	1	1	4
	Mood swings	3	22	0	25
	Nervousness	3	19	0	22
	Neurosis	0	1	0	1
	Nightmare	0	1	0	1
	Obsessive-compulsive disorder	1	0	0	1
	Panic attack	0	12	0	12
	Panic reaction	0	2	1	3
	Paranoia	0	6	0	6
	Persecutory delusion	0	5	0	5
	Personality change	1	3	0	4
	Personality disorder	1	0	0	1
	Poromania	0	1	0	1
	Psychiatric decompensation	0	1	0	1
	Psychiatric symptom	0	4	0	4
	Psychogenic seizure	0	1	0	1
	Psychotic disorder	4	6	0	10
	Reading disorder	0	3	0	3
	Restlessness	1	6	0	7
	Schizophrenia	0	6	0	6
	Self esteem decreased	0	1	0	1
	Sleep disorder	4	6	0	10
	Social avoidant behaviour	0	2	0	2
	Somatoform disorder neurologic	0	1	0	1
	Stress	0	4	1	5
	Substance-induced psychotic disorder	0	4	0	4
	Suicidal ideation	5	37	0	42
	Suicide attempt	0	28	0	28
	Tachyphrenia	0	2	0	2
Tearfulness	1	1	0	2	
Tension	2	1	0	3	
Thinking abnormal	0	12	0	12	
Transient psychosis	1	0	0	1	
Verbigeration	0	1	0	1	
Withdrawal syndrome	0	1	0	1	
	Anuria	1	2	0	3
	Azotaemia	2	1	0	3
	Bilirubinuria	0	2	0	2
	Bladder dilatation	0	2	0	2
	Bladder disorder	0	2	0	2
	Bladder irritation	0	2	0	2
	Bladder neck obstruction	0	1	0	1
	Bladder obstruction	0	2	0	2
	Bladder pain	1	1	0	2
	Bladder spasm	0	3	0	3
	Calculus bladder	0	1	0	1
	Chromaturia	0	8	0	8
	Dysuria	3	31	0	34
	Glomerulonephritis	1	0	0	1
	Glomerulonephritis membranoproliferative	0	1	0	1

Reaction SOC	Reaction PT	Leuprorelin			
		European Economic Area	Non European Economic Area	Not Specified	Total
Renal	Haematuria	9	28	0	37
	Haemorrhage urinary tract	1	0	0	1
	Hydronephrosis	4	7	0	11
	Hypertonic bladder	1	1	0	2
	IgA nephropathy	0	2	0	2
	Incontinence	0	5	0	5
	Micturition disorder	0	2	0	2
	Micturition urgency	0	2	0	2
	Nephrolithiasis	0	9	0	9
	Nephropathy	0	1	0	1
	Nephrotic syndrome	3	7	0	10
	Neurogenic bladder	0	1	0	1
	Nocturia	1	8	0	9
	Obstructive uropathy	0	3	0	3
	Oliguria	0	5	0	5
	Pollakiuria	2	30	0	32
	Polyuria	1	5	0	6
	Proteinuria	0	4	0	4
	Renal cortical necrosis	1	0	0	1
	Renal cyst	0	2	0	2
	Renal disorder	0	5	0	5
	Renal failure	6	30	0	36
	Renal failure acute	1	21	0	22
	Renal failure chronic	1	4	0	5
	Renal impairment	1	11	0	12
	Renal pain	0	3	0	3
	Renal tubular disorder	0	2	0	2
	Renal vein thrombosis	0	1	0	1
	Tubulointerstitial nephritis	2	4	0	6
	Ureteric stenosis	0	2	0	2
	Urethral haemorrhage	0	1	0	1
	Urethral obstruction	0	1	0	1
	Urethral stenosis	0	1	0	1
	Urinary bladder haemorrhage	0	1	0	1
	Urinary incontinence	0	14	0	14
	Urinary retention	3	28	1	32
	Urinary tract disorder	0	3	0	3
	Urinary tract obstruction	0	3	0	3
	Urinary tract pain	0	4	0	4
	Urine flow decreased	0	5	0	5
	Acquired phimosis	0	1	0	1
	Adenomyosis	0	1	0	1
Adnexa uteri pain	1	1	0	2	
Amenorrhoea	5	11	0	16	
Atrophic vulvovaginitis	0	4	0	4	
Balanoposthitis	0	1	0	1	
Benign prostatic hyperplasia	0	6	0	6	
Breast atrophy	1	2	0	3	
Breast cyst	0	1	0	1	
Breast enlargement	0	5	0	5	
Breast mass	0	4	0	4	
Breast pain	0	9	0	9	
Breast swelling	0	1	0	1	
Breast tenderness	0	7	0	7	
Cervical discharge	0	1	0	1	
Cervical polyp	0	1	0	1	
Cervix disorder	0	2	0	2	
Dysmenorrhoea	1	2	0	3	
Endometrial hyperplasia	0	1	0	1	
Endometrial hypertrophy	0	1	0	1	
Endometrial metaplasia	2	0	0	2	
Endometriosis	2	16	0	18	
Enlarged clitoris	0	1	0	1	
Epididymitis	0	2	0	2	

Reaction SOC	Reaction PT	Leuprorelin			
		European Economic Area	Non European Economic Area	Not Specified	Total
Repro	Erectile dysfunction	4	14	0	18
	Galactorrhoea	1	6	0	7
	Genital discharge	0	1	0	1
	Genital haemorrhage	0	30	0	30
	Gynaecomastia	2	15	0	17
	Haemorrhagic ovarian cyst	0	3	0	3
	Hydrometra	0	3	0	3
	Infertility female	0	1	0	1
	Menometrorrhagia	0	5	0	5
	Menopausal symptoms	2	9	0	11
	Menorrhagia	1	31	0	32
	Menstrual disorder	0	4	0	4
	Menstruation irregular	0	7	0	7
	Metrorrhagia	2	44	1	47
	Nipple pain	0	2	0	2
	Oedema genital	1	0	0	1
	Organic erectile dysfunction	3	0	0	3
	Ovarian cyst	6	18	0	24
	Ovarian cyst ruptured	0	9	0	9
	Ovarian disorder	1	3	0	4
	Ovarian enlargement	0	6	0	6
	Ovarian failure	0	2	0	2
	Ovarian haemorrhage	1	0	0	1
	Ovarian hyperstimulation syndrome	8	17	0	25
	Ovarian rupture	0	1	0	1
	Ovarian torsion	0	1	0	1
	Ovulation disorder	0	1	0	1
	Pelvic adhesions	0	1	0	1
	Pelvic fluid collection	0	1	0	1
	Pelvic haemorrhage	0	1	0	1
	Pelvic pain	2	32	0	34
	Penile haemorrhage	0	2	0	2
	Penile size reduced	0	2	0	2
	Penis disorder	0	1	0	1
	Perineal pain	1	0	0	1
	Polycystic ovaries	1	3	0	4
	Premature menopause	1	1	0	2
	Premenstrual syndrome	1	0	0	1
	Prostatic haemorrhage	1	1	0	2
	Prostatic obstruction	0	1	0	1
	Prostatitis	1	2	0	3
	Prostatomegaly	0	2	0	2
	Scrotal disorder	0	2	0	2
	Scrotal irritation	1	0	0	1
	Scrotal oedema	0	1	0	1
	Scrotal pain	0	1	0	1
	Scrotal swelling	0	1	0	1
	Testicular atrophy	1	6	0	7
	Testicular disorder	0	3	0	3
	Testicular pain	2	5	0	7
Testicular swelling	0	2	0	2	
Uterine atrophy	0	1	0	1	
Uterine cervical laceration	0	2	0	2	
Uterine disorder	0	1	0	1	
Uterine enlargement	0	3	0	3	
Uterine fistula	0	1	0	1	
Uterine haemorrhage	2	15	0	17	
Uterine pain	0	1	0	1	
Uterine polyp	0	1	0	1	
Uterine tenderness	0	1	0	1	
Vaginal discharge	0	2	0	2	
Vaginal haemorrhage	3	40	0	43	
Vaginal laceration	0	2	0	2	
Vulval disorder	1	0	0	1	

Reaction SOC	Reaction PT	Leuprorelin			
		European Economic Area	Non European Economic Area	Not Specified	Total
	Vulvovaginal dryness	0	1	0	1
	Withdrawal bleed	0	1	0	1
Resp	Acute interstitial pneumonitis	1	0	0	1
	Acute pulmonary oedema	2	1	0	3
	Acute respiratory distress syndrome	2	8	0	10
	Acute respiratory failure	1	1	0	2
	Allergic granulomatous angiitis	2	0	0	2
	Alveolitis allergic	0	1	0	1
	Apnoea	0	4	0	4
	Asphyxia	1	0	0	1
	Aspiration	0	2	0	2
	Asthma	1	21	0	22
	Asthmatic crisis	2	0	0	2
	Atelectasis	0	3	0	3
	Brain hypoxia	0	1	0	1
	Bronchospasm	5	2	0	7
	Choking sensation	0	2	0	2
	Chronic obstructive pulmonary disease	3	6	0	9
	Cough	5	56	0	61
	Diaphragmatic paralysis	0	1	0	1
	Diffuse alveolar damage	0	1	0	1
	Dry throat	0	2	0	2
	Dysphonia	2	7	0	9
	Dyspnoea	30	191	0	221
	Dyspnoea exertional	1	18	0	19
	Emphysema	0	5	0	5
	Eosinophilic pneumonia	0	5	0	5
	Epistaxis	2	14	0	16
	Haemoptysis	0	8	0	8
	Haemothorax	0	1	0	1
	Hiccups	1	1	0	2
	Hydrothorax	1	0	0	1
	Hypercapnia	0	1	0	1
	Hyperventilation	2	6	0	8
	Hypocapnia	1	0	0	1
	Hypopnoea	0	1	0	1
	Hypoxia	4	27	0	31
	Increased upper airway secretion	0	3	0	3
	Interstitial lung disease	5	387	0	392
	Laryngeal oedema	1	4	0	5
	Laryngospasm	0	1	0	1
	Lung disorder	2	12	0	14
	Lung infiltration	0	2	0	2
	Nasal congestion	0	1	0	1
	Nasal discomfort	0	1	0	1
	Nasal inflammation	0	1	0	1
	Nasal obstruction	1	3	0	4
	Neonatal respiratory distress syndrome	1	1	0	2
	Nocturnal dyspnoea	0	1	0	1
Obstructive airways disorder	0	1	0	1	
Organising pneumonia	0	7	0	7	
Oropharyngeal discomfort	0	2	0	2	
Oropharyngeal pain	2	8	0	10	
Pharyngeal oedema	1	5	0	6	
Pleural calcification	0	1	0	1	
Pleural effusion	6	46	0	52	
Pleurisy	1	3	0	4	
Pleuritic pain	0	1	0	1	
Pneumonia aspiration	0	11	0	11	
Pneumonitis	1	3	0	4	
Pneumothorax	0	5	0	5	
Productive cough	1	11	0	12	
Pulmonary alveolar haemorrhage	0	4	0	4	
Pulmonary arterial hypertension	2	0	0	2	

Reaction SOC	Reaction PT	Leuprorelin			
		European Economic Area	Non European Economic Area	Not Specified	Total
	Pulmonary artery thrombosis	0	1	0	1
	Pulmonary congestion	0	2	0	2
	Pulmonary embolism	16	69	1	86
	Pulmonary fibrosis	3	14	0	17
	Pulmonary granuloma	0	4	0	4
	Pulmonary haemorrhage	1	1	0	2
	Pulmonary hypertension	0	9	0	9
	Pulmonary infarction	0	8	0	8
	Pulmonary mass	0	1	0	1
	Pulmonary oedema	0	22	0	22
	Pulmonary thrombosis	0	3	0	3
	Pulmonary vascular disorder	1	0	0	1
	Rales	1	1	0	2
	Respiration abnormal	0	1	0	1
	Respiratory arrest	1	7	0	8
	Respiratory depression	0	1	0	1
	Respiratory disorder	2	10	0	12
	Respiratory distress	8	7	0	15
	Respiratory failure	3	25	0	28
	Respiratory gas exchange disorder	0	1	0	1
	Respiratory tract congestion	0	2	0	2
	Rhinorrhoea	1	3	0	4
	Rhonchi	1	0	0	1
	Sinus disorder	0	1	0	1
	Sinus polyp	0	1	0	1
	Sleep apnoea syndrome	0	5	0	5
	Sneezing	0	1	0	1
	Sputum discoloured	1	0	0	1
	Sputum increased	0	2	0	2
	Stridor	0	3	0	3
	Tachypnoea	2	6	0	8
	Throat irritation	1	1	0	2
	Throat tightness	0	2	0	2
	Tracheal stenosis	0	1	0	1
	Upper-airway cough syndrome	0	2	0	2
	Vocal cord polyp	1	0	0	1
	Wheezing	2	11	0	13
	Yawning	0	1	0	1
	Acanthosis nigricans	0	1	0	1
	Acne	3	9	0	12
	Acne cystic	0	1	0	1
	Actinic keratosis	0	2	0	2
	Acute febrile neutrophilic dermatosis	1	0	0	1
	Acute generalised exanthematous pustulosis	2	0	0	2
	Alopecia	7	26	0	33
	Angioedema	4	8	0	12
	Blister	0	5	0	5
	Cold sweat	2	12	0	14
	Cutaneous lupus erythematosus	1	0	0	1
	Decubitus ulcer	0	4	0	4
	Dermal cyst	0	1	0	1
	Dermatitis	3	8	0	11
	Dermatitis allergic	2	0	0	2
	Dermatitis atopic	1	0	0	1
	Dermatitis bullous	1	2	0	3
	Dermatitis contact	1	0	0	1
	Dermatitis exfoliative	2	6	0	8
	Dermatosis	1	0	0	1
	Drug eruption	1	11	0	12
	Drug rash with eosinophilia and systemic symptoms	2	3	0	5
	Dry skin	3	4	0	7
	Ecchymosis	2	3	0	5
	Eczema	10	10	0	20
	Eczema asteatotic	1	0	0	1

Reaction SOC	Reaction PT	Leuprorelin			
		European Economic Area	Non European Economic Area	Not Specified	Total
Skin	Erythema	10	25	0	35
	Erythema multiforme	1	8	0	9
	Excessive granulation tissue	0	3	0	3
	Fixed eruption	1	0	0	1
	Generalised erythema	0	9	0	9
	Haemorrhage subcutaneous	0	4	0	4
	Hair growth abnormal	1	0	0	1
	Hair texture abnormal	0	2	0	2
	Heat rash	0	2	0	2
	Henoch-Schonlein purpura	2	4	0	6
	Hirsutism	0	2	0	2
	Hyperhidrosis	14	60	2	76
	Hyperkeratosis	1	0	0	1
	Hypertrichosis	1	0	0	1
	Increased tendency to bruise	0	1	0	1
	Keloid scar	0	1	0	1
	Leukocytoclastic vasculitis	1	4	0	5
	Lichen planus	0	1	0	1
	Lichen sclerosus	0	1	0	1
	Lipohypertrophy	0	1	0	1
	Night sweats	3	21	0	24
	Pain of skin	1	1	0	2
	Palmoplantar keratoderma	1	0	0	1
	Papule	1	1	0	2
	Pemphigoid	1	2	0	3
	Pemphigus	1	0	0	1
	Petechiae	1	0	0	1
	Photosensitivity reaction	2	1	0	3
	Pigmentation disorder	0	2	0	2
	Pruritus	24	34	0	58
	Pruritus generalised	4	4	0	8
	Psoriasis	1	0	0	1
	Purpura	1	6	0	7
	Rash	24	53	0	77
	Rash erythematous	3	5	0	8
	Rash generalised	7	10	0	17
	Rash macular	5	3	0	8
	Rash maculo-papular	3	2	0	5
	Rash papular	3	0	0	3
	Rash pruritic	2	2	0	4
	Rosacea	0	1	0	1
	Scar	1	2	0	3
	Seborrhoea	0	2	0	2
	Skin atrophy	1	0	0	1
	Skin burning sensation	1	3	0	4
	Skin depigmentation	1	0	0	1
	Skin discolouration	7	5	1	13
	Skin disorder	3	3	0	6
	Skin erosion	0	1	0	1
	Skin exfoliation	2	4	0	6
	Skin fissures	2	0	0	2
	Skin haemorrhage	1	0	0	1
	Skin hyperpigmentation	1	0	0	1
Skin hypertrophy	1	0	0	1	
Skin hypopigmentation	0	1	0	1	
Skin induration	1	1	0	2	
Skin irritation	0	1	0	1	
Skin lesion	3	1	0	4	
Skin mass	1	3	0	4	
Skin necrosis	1	2	0	3	
Skin oedema	0	1	0	1	
Skin reaction	4	1	0	5	
Skin swelling	0	1	0	1	
Skin tightness	1	0	0	1	

Reaction SOC	Reaction PT	Leuprorelin			
		European Economic Area	Non European Economic Area	Not Specified	Total
	Skin toxicity	1	0	0	1
	Skin ulcer	4	8	0	12
	Stevens-Johnson syndrome	1	11	0	12
	Subcutaneous nodule	3	4	0	7
	Sweat gland disorder	0	2	0	2
	Swelling face	1	11	0	12
	Toxic epidermal necrolysis	1	2	0	3
	Toxic skin eruption	3	5	0	8
	Urticaria	12	51	0	63
	Vascular purpura	2	0	0	2
Yellow skin	0	3	0	3	
SocCi	Activities of daily living impaired	0	7	0	7
	Bedridden	0	7	0	7
	Disability	0	1	0	1
	Gambling	1	0	0	1
	Impaired driving ability	0	3	0	3
	Impaired work ability	0	4	0	4
	Menopause	0	1	0	1
	Verbal abuse	0	2	0	2
	Walking aid user	0	3	0	3
Walking disability	0	2	0	2	
Surg	Abortion induced	2	4	0	6
	Abscess drainage	0	1	0	1
	Bilateral orchidectomy	0	1	0	1
	Bladder catheter replacement	1	0	0	1
	Caesarean section	1	1	0	2
	Cardiac pacemaker insertion	0	1	0	1
	Cervix cerclage procedure	0	1	0	1
	Cholecystectomy	0	2	0	2
	Colectomy	0	1	0	1
	Contraceptive diaphragm	1	0	0	1
	Coronary artery bypass	0	3	0	3
	Endodontic procedure	0	1	0	1
	Endometrial ablation	0	1	0	1
	Hospitalisation	2	3	0	5
	Hysterectomy	0	1	0	1
	Intraocular lens implant	1	0	0	1
	Knee arthroplasty	0	1	0	1
	Limb operation	1	0	0	1
	Nasal septal operation	0	1	0	1
	Off label use	4	9	0	13
	Oral surgery	0	1	0	1
	Orchidectomy	0	1	0	1
	Prostatectomy	0	3	0	3
	Radiotherapy	0	1	0	1
	Skin operation	1	0	0	1
	Spinal decompression	0	1	0	1
	Spinal fusion surgery	0	1	0	1
	Surgery	0	4	0	4
	Thyroidectomy	0	1	0	1
	Tooth extraction	1	0	0	1
Transurethral prostatectomy	3	0	0	3	
Vasodilation procedure	0	1	0	1	
Venous operation	0	2	0	2	
	Air embolism	0	1	0	1
	Angiopathy	0	2	0	2
	Aortic aneurysm	0	4	0	4
	Aortic aneurysm rupture	0	1	0	1
	Aortic arteriosclerosis	0	2	0	2
	Arterial occlusive disease	0	2	0	2
	Arteriosclerosis	0	4	0	4
	Arteritis	0	1	0	1
	Blood pressure fluctuation	0	4	0	4
	Blood pressure inadequately controlled	0	1	0	1

Reaction SOC	Reaction PT	Leuprorelin			
		European Economic Area	Non European Economic Area	Not Specified	Total
Vasc	Circulatory collapse	11	6	0	17
	Deep vein thrombosis	8	63	0	71
	Diastolic hypertension	0	1	0	1
	Embolism	1	9	0	10
	Embolism arterial	1	0	0	1
	Femoral artery occlusion	0	4	0	4
	Flushing	4	14	0	18
	Granulomatosis with polyangiitis	1	0	0	1
	Haematoma	1	7	0	8
	Haemorrhage	7	20	0	27
	Hot flush	35	246	1	282
	Hypertension	9	85	0	94
	Hypertensive crisis	0	1	0	1
	Hypotension	4	23	0	27
	Infarction	1	0	0	1
	Inferior vena caval occlusion	0	1	0	1
	Intermittent claudication	1	0	0	1
	Ischaemia	0	2	0	2
	Jugular vein thrombosis	0	1	0	1
	Microangiopathy	0	2	0	2
	Microscopic polyangiitis	0	2	0	2
	Neovascularisation	1	0	0	1
	Orthostatic hypotension	1	2	0	3
	Pallor	1	23	0	24
	Pelvic venous thrombosis	0	2	0	2
	Peripheral arterial occlusive disease	0	2	0	2
	Peripheral artery thrombosis	0	2	0	2
	Peripheral coldness	0	4	0	4
	Peripheral embolism	1	2	0	3
	Peripheral vascular disorder	1	3	0	4
	Phlebitis	0	4	0	4
	Phlebitis superficial	0	1	0	1
	Phlebolith	0	1	0	1
	Poor peripheral circulation	0	1	0	1
	Shock	0	13	0	13
	Subclavian vein thrombosis	0	2	0	2
	Temporal arteritis	0	1	0	1
	Thrombophlebitis	1	7	0	8
	Thrombophlebitis superficial	0	3	0	3
	Thrombosis	0	32	0	32
	Varicose vein	0	1	0	1
	Vascular occlusion	0	1	0	1
	Vasculitis	4	4	0	8
	Vasodilatation	1	55	0	56
	Vein disorder	1	1	0	2
Vena cava thrombosis	0	1	0	1	
Venous thrombosis	1	7	0	8	
Venous thrombosis limb	3	6	0	9	