

			Goserelin			
Reaction SOC	Reaction PT	European Economic	Non European Economic	Not		
	Agranulocytosis	Area 1	Area 0	Specified 0	Total	
	Anaemia	2	22		24	
	Anaemia haemolytic autoimmune	0	3		3	
	Aplasia pure red cell Aplastic anaemia	0			1 1	
	Autoimmune thrombocytopenia	1	0	_	1	
	Bone marrow failure	1	2	0	3	
	Bone marrow oedema	1 1	7		1 8	
	Disseminated intravascular coagulation Eosinophilia	1	1		2	
	Febrile neutropenia	0	1		1	
	Haemolytic anaemia	1	1		2	
	Haemolytic uraemic syndrome Haemorrhagic diathesis	0	1 1	_	1 1	
Blood	Iron deficiency anaemia	0	1		1	
	Leukaemoid reaction	1	0		1	
	Leukocytosis Leukopenia	0	<u>1</u> 5		<u>1</u> 5	
	Lymphadenopathy	1	3		4	
	Lymphopenia	4	0	0	4	
	Neutropenia	1	8		9	
	Normochromic normocytic anaemia Pancytopenia	1 3	0 12	0	1 15	
	Red blood cell abnormality	1	0		1	
	Spleen disorder	0	1	_	1	
	Splenomegaly	0	1	0	1	
	Thrombocytopenia Thrombocytosis	2	20	0	22 1	
	White blood cell disorder	0	1	0	1	
	Acute myocardial infarction	0	4		4	
	Angina pectoris Angina unstable	3	0 2		3	
	Arrhythmia	2	9		11	
	Arrhythmia supraventricular	0	2	0	2	
	Arteriospasm coronary	1	0		1	
	Atrial fibrillation Atrial flutter	2	5			
	Atrioventricular block complete	0	1		1	
	Atrioventricular block second degree	0	1		1	
	Bradycardia Bundle branch block left	3 0	4			
	Cardiac arrest	1	5		6	
	Cardiac disorder	1	2		3	
	Cardiac failure Cardiac failure acute	3				
	Cardiac failure acute Cardiac failure congestive	1	9		1 10	
Card	Cardio-respiratory arrest	0	1	0		
	Cardiotoxicity	1	0		1	
	Cardiovascular disorder Coronary artery dissection	0	1 1		1 1	
	Left ventricular failure	1	0			
	Myocardial infarction	7	27	0		
	Myocardial ischaemia Neonatal tachycardia	0	2			
	Palpitations	5	5			
	Pericardial effusion	0	1	0		
	Pericarditis	0			1	
	Sick sinus syndrome Sinus bradycardia	1 0	0			
	Sinus tachycardia	0	2	_	2	
	Tachycardia	4	4	0	8	
	Ventricular extrasystoles Ventricular fibrillation	1 0	3		<u>4</u>	
	Atrial septal defect	0	1			
	Congenital cystic kidney disease	0	1	0	1	
	Haemangioma of retina	0				
Cong	Hamartoma Limb malformation	0	1 0			
	Melkersson-Rosenthal syndrome	1	0		1	
	Neurofibromatosis	0	1	0	1	
	Phimosis Deafness	0	1 1			
	Dearness Ear disorder	1	0			
	Hyperacusis	1	0			



	Reaction PT		Goserelin			
Reaction SOC		European Economic Area	Non European Economic Area	Not Specified	Total	
Ear	Hypoacusis	1	0	0	1	
	Sudden hearing loss	1	1	0	2	
	Tinnitus	2	2	0	4	
	Vertigo Androgen deficiency	4 0	2	0	6 2	
	Basedow's disease	1	1	0	2	
	Cushing's syndrome	0	1	0	1	
	Diabetes insipidus	0	3	0	3	
	Hyperprolactinaemia	0	1	0	1	
	Hyperthyroidism Hypogonadism	0	2 1	0	2 1	
Endo	Hypogonadism male	0	1	0	1	
2.100	Hypopituitarism	0	2	0	2	
	Hypothyroidism	1	2	0	3	
	Pituitary haemorrhage	0	10	0	10	
	Pituitary infarction	2	1	0	3	
	Secondary hypogonadism Thyroid haemorrhage	0	1 0	0	1 1	
	Thyroid Haemorriage Thyroiditis subacute	0	1	0	1	
	Asthenopia	1	0	0	1	
	Blindness	2	5	0	7	
	Cataract	0	2	0	2	
	Cataract subcapsular Cystoid macular oedema	0	1 1	0	1 1	
	Diplopia	2	2	0	4	
	Dry eye	0	1	0	1	
	Exophthalmos	1	0	0	1	
	Eye irritation	0	2	0	2	
	Eye movement disorder	0	1	0	1	
	Eye swelling Eyelid oedema	1 1	1 1	0	2 2	
	Eyelid ptosis	0	2	0	2	
	Night blindness	1	0	0	1	
Eye	Ocular discomfort	1	1	0	2	
	Ophthalmoplegia	0	1	0	1	
	Optic ischaemic neuropathy Papilloedema	0	1	0	1 2	
	Pupillary reflex impaired	2 0	0 1	0	1	
	Retinal depigmentation	0	1	0	1	
	Retinal detachment	1	1	0	2	
	Retinal haemorrhage	0	1	0	1	
	Retinal vascular disorder	0	1	0	1	
	Scleritis Uveitis	0	1	0	1	
	Vision blurred	0	2	0	<u>2</u> 3	
	Visual acuity reduced	5	3	0	8	
	Visual impairment	1	4	0	5	
	Vitreous haemorrhage	1	0		1	
	Abdominal discomfort	1	0	0	1	
	Abdominal distension Abdominal mass	1	7 0	0	9 1	
	Abdominal mass Abdominal pain	5	16	0	21	
	Abdominal pain lower	0		0	1	
	Abdominal pain upper	6	6	0	12	
	Acute abdomen	0	1	0	1	
	Anal haemorrhage	0	1	0	1	
	Aphagia Aptyalism	0	<u>1</u>	0	1 1	
	Ascites	4	4	0	8	
	Cheilitis granulomatosa	1	0	0	1	
	Colitis	1	0	0	1	
	Colitis ischaemic	0		0	1	
	Colonic polyn	1 0	0 1	0	1 1	
	Colonic polyp Constipation	3	4	0	<u>1</u> 7	
	Diarrhoea	2	9		12	
	Diarrhoea haemorrhagic	1	0	0	1	
	Dry mouth	1	1	0	2	
	Duodenal ulcer	0	1	0	1	
	Duodenal ulcer haemorrhage	0		0	1	
	Dyspepsia Dysphagia	2	3	0	5 5	
	Enterocolitis	0	1	0	1	
	Faecal incontinence	0	1	0	1	



			Goserelin			
Reaction SOC	Reaction PT	European Economic	Non European Economic	Not		
	Faeces discoloured	Area 0	Area 1	Specified 0	Total	
	Faeces pale	1	0	0	1	
	Flatulence	2	0		2	
	Gastric dilatation Gastric ulcer	1 1	0 4		<u>1</u> 5	
Gastr	Gastric ulcer perforation	0	1	0	1	
Gasti	Gastritis erosive	0	1	0	1	
	Gastrointestinal haemorrhage Gastrointestinal ulcer haemorrhage	0	3 2		3 2	
	Gingival bleeding	1	0		1	
	Gingival recession	1	0	_	1	
	Gingival swelling Glossodynia	1	0 1		1 2	
	Haematemesis	0	2		2	
	Hypoaesthesia oral	1	0		1	
	Inguinal hernia Intestinal obstruction	1 0	0 2		<u>1</u> 2	
	Intestinal obstruction	0	1		1	
	Intra-abdominal haemorrhage	0	2		2	
	Lip swelling Melaena	2	0		2	
	Nausea	10	1 24		1 35	
	Necrotising colitis	0	1		1	
	Pancreatitis	1	0		1	
	Pancreatitis acute Paraesthesia oral	0	1 1	_	1 1	
	Polyp colorectal	0	1		1	
	Rectal ulcer	0	1		1	
	Retroperitoneal fibrosis Retroperitoneal haematoma	1 0	0 2		1 2	
	Stomatitis	1	1	0	2	
	Swollen tongue	1	0		1	
	Tongue ulceration Tooth discolouration	0	1 1		<u>1</u>	
	Tooth loss	1	0	_	1	
	Toothache	0	1		1	
	Upper gastrointestinal haemorrhage Vomiting	0	1 30		1 36	
	Abasia	0	30		30	
	Administration site pain	1	0	0	1	
	Administration site reaction Adverse drug reaction	0	2 1	0	2 1	
	Adverse event	0				
	Application site haematoma	0	5		5	
	Application site haemorrhage	0	3		3	
	Application site oedema Application site pain	0	1 2			
	Application site reaction	1	0	1	2	
	Application site swelling	0	17		1 22	
	Asthenia Atrophy	5	17 2			
	Cardiac death	0	1	0	1	
	Chest discomfort	0	3			
	Chest pain Chills	5 4	7 6			
	Condition aggravated	3	2	0		
	Crying	1	1	0	2	
	Cyst Death	0 4	1 104			
	Device breakage	1	0			
	Device expulsion	1	1		2	
	Device failure Device malfunction	2	0 1		2	
	Discomfort	0	1	0	1	
	Disease progression	1	27	0		
	Drug ineffective Drug interaction	1 2	16 8			
	Drug intolerance	0	1			
	Face oedema	0	3	0	3	
	Fat tissue increased Fatigue	1 8	1 22		2 31	
	Feeling abnormal	1	1			
	Feeling cold	2	2	0	4	
	Feeling hot	1	3	1	5	



			Goserelin			
Reaction SOC	Reaction PT	European Economic	Non European Economic	Not		
	Foreign body reaction	Area 0	Area 1	Specified 0	Total	
	Gait disturbance	4		1	12	
	General physical health deterioration	1	3		4	
	Generalised oedema	0			3	
	Granuloma Hunger	0			3 1	
	Ill-defined disorder	0			1	
	Impaired healing	0			1	
	Implant site effusion	0			1	
	Implant site haematoma	0			2 1	
	Implant site haemorrhage Implant site inflammation	1			1	
01	Implant site irritation	1	0		1	
Genrl	Implant site mass	1	0	0	1	
	Implant site pain	1	0		1	
	Implant site reaction	2	0		2	
	Inflammation Influenza like illness	1 0	0 4		<u>1</u> 4	
	Inhibitory drug interaction	0			1	
	Injection site abscess sterile	0		0	1	
	Injection site erythema	0			1	
	Injection site extravasation	2	0		2	
	Injection site granuloma	0			1.0	
	Injection site haematoma Injection site haemorrhage	1 0	15 15		16 15	
	Injection site induration	0	4		4	
	Injection site inflammation	1	1		2	
	Injection site mass	1	1		2	
	Injection site oedema	1	0		1	
	Injection site pain Injection site rash	1 1	7	0	8 2	
	Injection site reaction	2	5			
	Injection site swelling	0			2	
	Irritability	2	3		5	
	Local swelling	1	0		1	
	Localised oedema Malaise	5	1 21	0	3 26	
	Medical device complication	0			1	
	Multi-organ disorder	0			1	
	Multi-organ failure	0	3	0	3	
	No adverse event	0			1	
	No therapeutic response Nodule	1 0	0		1	
	Obstruction	0			1	
	Oedema	5			11	
	Oedema due to hepatic disease	1	0	0	1	
	Oedema peripheral	8			22	
	Pain	3			21	
	Patient-device incompatibility Pelvic mass	2			2 1	
	Performance status decreased	0			1	
	Product adhesion issue	1	0		1	
	Pseudocyst	0			1	
	Pyrexia	6			41	
	Secretion discharge Spinal pain	1 0	2		<u>1</u>	
	Sudden death	0			2	
	Swelling	1	6		7	
	Syringe issue	1	0		1	
	Thirst	2	2		4	
	Ulcer Unevaluable event	0			<u>1</u> 3	
	Acute hepatic failure	2	3		3 4	
	Alcoholic liver disease	1	0		1	
	Autoimmune hepatitis	0			1	
	Biliary tract disorder	1	0	0	1	
	Cholangitis	1	0		1	
	Cholecystitis	1	0		1	
	Cholelithiasis Cholestasis	0	2		2 1	
	Cholestatic liver injury	0			3	
	Drug-induced liver injury	0			4	
	Hepatic atrophy	1		0	1	
	Hepatic cirrhosis	1	0	0	1	



		Goserelin			
Reaction SOC	Reaction PT	European Economic Area	Non European Economic Area	Not Specified	Total
	Hepatic cyst ruptured	1	0		1
	Hepatic failure	0	4		4
	Hepatic function abnormal Hepatic infarction	0	63 1	0	63 1
Hepat	Hepatic necrosis	1	1		2
	Hepatic steatosis	0	4	_	4
	Hepatitis	0	3		3
	Hepatitis acute	3	1		4
	Hepatitis cholestatic	2	<u>1</u> 7	0	3 8
	Hepatitis fulminant Hepatitis toxic	1 1	0		1
	Hepatocellular injury	1	2	0	3
	Hepatomegaly	0	2		2
	Hepatotoxicity	0	3		3
	Hyperbilirubinaemia	0	1	0	1
	Jaundice Jaundice cholestatic	1 1	15 3		16 4
	Liver disorder	0	24		24
	Liver injury	1	4		5
	Non-alcoholic steatohepatitis	0	1	0	1
	Anaphylactic reaction	4	6		10
	Anaphylactic shock Anaphylactoid reaction	0	1 1	_	2 1
Immun	Anti-neutrophil cytoplasmic antibody positive vasculitis	0	1	0	1
-	Hypersensitivity	14	13	0	27
	Immune system disorder	1	0		1
	Immunosuppression	1	0	_	1
	Multiple allergies Abdominal abscess	0	1 1	0	1
	Abscess bacterial	0	1		1 1
	Abscess neck	1	0		1
	Alpha haemolytic streptococcal infection	0	1	0	1
	Bacterial infection	1	0	_	1
	Beta haemolytic streptococcal infection	0	1		1
	Bronchitis Bronchopneumonia	0	2 1		2 1
	Cellulitis	0	1	_	1
	Cystitis	1	1	0	2
	Folliculitis	0	1		1
	Gastroenteritis viral	0	1	0	1
	Gingivitis Hepatitis C	2	1 1	0	3 1
	Impetigo	1	0		1
	Implant site abscess	1	0		
	Infection	0	2		
	Influenza	0	2	0	
	Injection site abscess Injection site cellulitis	0	5 1		5 1
	Injection site cenditis Injection site infection	0	3		
	Laryngitis	0	1		
	Lower respiratory tract infection	1	0		
Infec	Meningitis viral	0	1		
200	Nasopharyngitis	0	1		
	Neisseria infection Oral candidiasis	0	1 1		1 2
	Osteomyelitis	2	2		
	Parotitis	0	1		
	Pharyngeal abscess	1	0		
	Pneumocystis jiroveci pneumonia	0	1		1
	Pneumonia Pneumonia hactorial	1 0	16 1		
	Pneumonia bacterial Pulmonary tuberculosis	0	3		
	Purulent discharge	0	1		
	Rash pustular	0	0	1	1
	Renal abscess	0	1		
	Respiratory tract infection	1	1		
	Sepsis Septic shock	0	5 1		
	Sinusitis	0	1	_	
	Staphylococcal bacteraemia	0	2		
	Subcutaneous abscess	0	1		
	Tuberculosis	0	1		1
Ī	Urethritis	1	0	0	1



	[Goserelin			
Reaction SOC	Reaction PT	European Economic Area	Non European Economic Area	Not Specified	Total	
	Urinary tract infection	Area 0	Area 8	Specified 0	10tai 8	
	Urosepsis	0	1	0	1	
	Wound infection Abdominal injury	0	1 1	0	<u>1</u>	
	Arterial injury	0	2	0	2	
	Contusion	1	2	0	3	
	Drug administration error	2	3 1	0	5 1	
	Drug dispensing error Drug dose omission	4	1	0		
	Drug name confusion	0	1	0	1	
	Drug prescribing error	1	1	0	2	
	Fall Femoral neck fracture	2	5 0	0		
	Femur fracture	2	1	0	3	
	Foot fracture	0	2	0	2	
	Foreign body	1	0	0	1	
	Fracture Head injury	1 0	0 1	0	1	
	Hip fracture	0	2	0	2	
	Inappropriate schedule of drug administration	1	0	0	1	
	Incorrect dose administered	1	0	0	1	
	Incorrect route of drug administration Injury	0	<u>3</u>	0	3 2	
Inj&P	Laceration	1	0	0	1	
	Lower limb fracture	1	0	0	1	
	Lumbar vertebral fracture	0 2	1 11	0	<u>1</u>	
	Maternal exposure during pregnancy Medication error	1	7	0	13 8	
	Overdose	2	4	0	6	
	Radiation pneumonitis	0	1	0	1	
	Rib fracture	0	1 2	0	1	
	Road traffic accident Sciatic nerve injury	0	1	0	2 1	
	Spinal compression fracture	0	3	0	3	
	Spinal fracture	1	1	0	2	
	Subcutaneous haematoma Subdural haematoma	0	<u>4</u> 2	0	4 2	
	Tibia fracture	1	0	0	1	
	Upper limb fracture	1	1	0	2	
	Urostomy complication	0	1	0	1	
	Wound dehiscence Wrong drug administered	0	2 1	0	2	
	Wrong technique in drug usage process	2	2	0	4	
	Alanine aminotransferase increased	1	7	0	8	
	Amylase increased	0	1 1	0	1	
	Antinuclear antibody Aspartate aminotransferase increased	0	9	0	<u>1</u> 9	
	Bleeding time prolonged	0		0	2	
	Blood alkaline phosphatase increased	0	10	0	10	
	Blood bilirubin increased Blood calcium decreased	0	3 1	0	3 1	
	Blood chloride decreased	0	1	0	1	
	Blood cholesterol increased	3	3	0	6	
	Blood cortisol decreased	0		0	1	
	Blood count abnormal Blood creatine phosphokinase increased	0 2	1 0	0	1 2	
	Blood fibrinogen decreased	0	2	0	2	
	Blood follicle stimulating hormone decreased	3	0	0	3	
	Blood follicle stimulating hormone increased	0		0	3	
	Blood glucose abnormal Blood glucose increased	0 4	1 11	0	<u>1</u>	
	Blood immunoglobulin E increased	0	1	0	1	
	Blood lactate dehydrogenase increased	1	6	0	7	
	Blood luteinising hormone decreased	3	0	0	3	
	Blood luteinising hormone increased Blood potassium decreased	0		0	<u>1</u>	
	Blood potassium increased	0		0	1	
	Blood pressure decreased	0	3	0	. 3	
	Blood pressure increased	8	9	0	17	
	Blood prolactin increased Blood sodium decreased	0	1	0	<u>1</u> 1	
	Blood sodium increased	0	2	0	2	
	Blood testosterone	0	1	0	1	
	Blood testosterone decreased	0	1	0	1	



	<u> </u>		Goserelin			
Reaction SOC	Reaction PT	European Economic Area	Non European Economic Area	Not Specified	Total	
	Blood testosterone increased	2	3		5 Total	
	Blood triglycerides increased	0	4		4	
	Blood urea increased Blood uric acid increased	0	1 2	0	<u>1</u> 2	
	Blood urine present	0	2	0	2	
	Body temperature increased	1	0	0	1	
	Bone densitometry	1	0	0	1	
	Bone density decreased C-reactive protein increased	2	0 2	0	<u>2</u> 5	
	Carbohydrate antigen 19-9 increased	0	1	0	1	
	Carcinoembryonic antigen increased	2	1	0	3	
	Chest X-ray abnormal Eosinophil count decreased	0	1 1	0	1	
	Eosinophil count increased	0	2	0	2	
	Exercise test abnormal	0	1	0	1	
Inv	Foetal heart rate abnormal	0	1	0	1	
	Gamma-glutamyltransferase increased Glycosylated haemoglobin increased	1 0	<u>4</u>	0	5 1	
	Haematocrit decreased	1	1	0	2	
	Haemoglobin decreased	2	6	0	8	
	Haemoglobin increased	1	0	0	1	
	Head circumference abnormal Heart rate abnormal	0	1 1	0	1 1	
	Heart rate decreased	0	1	0	1	
	Heart rate increased	3	0	0	3	
	Heart rate irregular	1	0	0	1	
	Hepatic enzyme increased Hormone level abnormal	3	6 1	0	9	
	International normalised ratio abnormal	0	1	0	1	
	Lipase increased	0	1	0	1	
	Lipids abnormal	0	<u>2</u> 7	0	2	
	Liver function test abnormal Lymphocyte count decreased	0	1	0	1	
	Lymphocyte stimulation test	0	2	0	2	
	Neutrophil count decreased	0	1	0	1	
	Nuclear magnetic resonance imaging abnormal Oestradiol increased	1 2	0 1	0	<u>1</u>	
	Platelet count decreased	0	9	0	9	
	Platelet count increased	1	0	0	1	
	Precancerous cells present	0	1	0	1	
	Prostatic specific antigen Prostatic specific antigen abnormal	0	1	0	<u>1</u>	
	Prostatic specific antigen decreased	0	1	0		
	Prostatic specific antigen increased	4	23	0	27	
	Protein total decreased Prothrombin level increased	0	1 1	0		
	Prothrombin time shortened	1	0			
	Pulmonary function test decreased	0	1	0		
	Quality of life decreased	0	2	0	2	
	Red blood cell count decreased Red blood cell sedimentation rate increased	0	1 0	0		
	Rheumatoid factor positive	1	0	0	1	
	Semen volume decreased	0	1	0	1	
	Transaminases increased	0	3	0		
	Troponin increased Tumour marker increased	0	<u>1</u> 2	0	1 2	
	Ultrasound thyroid abnormal	1	0		1	
	Urine output decreased	0	2	0		
	Weight decreased Weight increased	4 7	16 32	<u>0</u>	20 40	
	White blood cell count decreased	0	7	0	7	
	White blood cell count increased	0	1	0	1	
	Acidosis	0	3		3	
	Alcohol intolerance Appetite disorder	0	1 2	0		
	Cell death	0	1	0	1	
	Decreased appetite	4	12	0	16	
	Dehydration Disk the second like to a se	0	2	0	2	
	Diabetes mellitus Diabetes mellitus inadequate control	3	22 2	0		
	Diabetic ketoacidosis	0	3	0		
	Dyslipidaemia	0	1	0	1	
	Fluid retention	2	2	0		
	Glucose tolerance impaired	1	0	0	1	



	Reaction PT		Goserelin			
Reaction SOC		European Economic Area	Non European Economic Area	Not Specified	Total	
	Gout	Area 0	Area 1	Specified 0	10tai	
	Hypercalcaemia	0	2	0	2	
Metab	Hypercholesterolaemia Hyperglycaemia	0 2	1 10	0	1 12	
rictab	Hyperlipidaemia	0	1	0	1	
	Hyperuricaemia	0	2	0	2	
	Hypocalcaemia	1	3	0	4	
	Hypoglycaemia Hypokalaemia	1 0	2	0	3	
	Hyponatraemia	1	3	0	4	
	Hypophosphataemia	0	1	0	1	
	Increased appetite	0 2	2 0	0	<u>2</u> 2	
	Metabolic syndrome Obesity	0	1	0	1	
	Polydipsia	0	1	0	1	
	Shock hypoglycaemic	1	0	0	1	
	Tumour lysis syndrome Type 1 diabetes mellitus	0	3 1	0	3	
	Weight loss poor	0	1	0	1	
	Arthralgia	23	17	1	41	
	Arthritis	3	3	0	6	
	Arthropathy Back pain	1 7	0 15	0	1 22	
	Bone disorder	0	13	0	1	
	Bone pain	10	7	0	17	
	Camptocormia	1	0	0	1	
	Coccydynia Fasciitis	0	2 0	0	2 1	
	Fibromyalgia	0	1	0	1	
	Flank pain	0	0	1	1	
	Gouty arthritis	0	2	0	2	
	Groin pain Jaw disorder	0	1 0	0	1 1	
	Joint stiffness	1	1	1	3	
	Joint swelling	3	2	0	5	
	Mobility decreased	1	0	0	1	
	Muscle atrophy Muscle rigidity	4 0	1	0	<u>4</u>	
	Muscle spasms	2	1	0	3	
	Muscle twitching	0	1	0	1	
	Muscular weakness Musculoskeletal chest pain	13	12 1	0	25 1	
	Musculoskeletal pain	0	4	0	4	
Musc	Musculoskeletal stiffness	1	3	0	4	
	Myalgia	10	6	0	16	
	Myopathy Myositis	4 0	1	0	5 1	
	Neck pain	1	2	0	3	
	Osteoarthritis	0	3	0	3	
	Osteonecrosis	2	5	0	7	
	Osteonecrosis of jaw Osteopenia	2	2 1	0	4 2	
	Osteoporosis	6	3	0	9	
	Osteoporotic fracture	1	6	0	7	
	Pain in extremity	3 0	7 1	0	10	
	Pain in jaw Pathological fracture	2	1	0	3	
	Polyarthritis	2	0	0	2	
	Polymyalgia rheumatica	0	1	0	1	
	Polymyositis	1	2	0	3	
	Pubic pain Rhabdomyolysis	0	1 2	0	<u>1</u>	
	Rheumatoid arthritis	1	1	0	2	
	Scoliosis	0	2	0	2	
	Sensation of heaviness	1	0	0	1	
	Tendon disorder Tenosynovitis	1 0	0 1	0	1	
	Trismus	1	0	0	1	
	Acute lymphocytic leukaemia	0	1	0	1	
	Acute myeloid leukaemia	1	4	0	5	
	Adenocarcinoma Basal cell carcinoma	0	1 1	0	1	
	Benign lung neoplasm	0	1	0	1	
	Bladder cancer	2	1	0	3	



			Goserelin			
Reaction SOC	Reaction PT	European Economic	Non European Economic	Not		
	Diadday a carlage	Area	Area	Specified	Total	
	Bladder neoplasm Bone neoplasm malignant	0		0		
	Brain neoplasm benign	0		0	1	
	Breast cancer	2	4	0	ϵ	
	Breast cancer female	1	1	0	2	
	Breast cancer male	0		0		
	Breast cancer metastatic Breast cancer stage II	0	2	0		
	Carcinoid tumour of the caecum	0	1	0		
	Cervix carcinoma	1	1	0	2	
	Chondroma	0	1	0	1	
	Colon adenoma	0	2	0		
	Degeneration of uterine leiomyoma	1	1	0		
	Endometrial cancer Extramammary Paget's disease	0	1 1	0	1	
	Gastric cancer	1	4		5	
	Gastrointestinal carcinoma	0		0	1	
	Hepatic neoplasm	0	2	0	2	
	Hepatic neoplasm malignant	2	1	0	3	
	Laryngeal cancer	0	1	0		
	Leiomyoma Leukaemia	0	<u>3</u>	0	3	
	Leukaemia recurrent	0	1	0	3 1	
	Leukoerythroblastosis	0	1	0	<u>.</u> 1	
	Lung neoplasm malignant	0	4	0	4	
	Malignant neoplasm progression	0	10	0	10	
	Meningioma	1	0	0	1	
	Metastases to bone	2	10		12	
Neopl	Metastases to central nervous system	0	2	0	2	
	Metastases to liver Metastases to lymph nodes	1	0			
	Metastases to spine	0	1	0		
	Metastasis	0		0	1	
	Metastatic neoplasm	0		0	2	
	Myelodysplastic syndrome	0	6	0	6	
	Myelofibrosis	0	1	0	1 1	
	Myeloid leukaemia Neoplasm	0	1 19	0	20	
	Neoplasm malignant	0	4	0		
	Osteochondroma	0		0	1	
	Ovarian cancer	1	1	0	2	
	Ovarian neoplasm	0		0	2	
	Pancreatic carcinoma	0		0	1	
	Pituitary tumour Pituitary tumour benign	0 2	7	0	4	
	Prolactin-producing pituitary tumour	0		0		
	Prostate cancer	3			18	
	Prostate cancer metastatic	1	12		13	
	Prostate cancer recurrent	0		0	1	
	Rectal cancer	0		0	2	
	Recurrent cancer Renal cancer	0	1 1	0	1	
	Sarcoma uterus	1	0			
	Skin cancer	1	1	0		
	Skin papilloma	0		0	1	
	Small cell lung cancer stage unspecified	0		0	1	
	Splenic neoplasm malignancy unspecified	0		0	1	
	Squamous cell carcinoma	0		0		
	Throat cancer Thyroid adenoma	0	1 0	0	1	
	Tumour flare	0		0		
	Tumour haemorrhage	0		0	1	
	Uterine cancer	0	2	0	2	
	Uterine leiomyoma	3	1	0	4	
	Altered state of consciousness	0		0		
	Amnesia	2	3	0		
	Anosmia Aqueductal stenosis	1 0	0	0	1	
	Ataxia	1	2	0		
	Axonal neuropathy	1	0			
	Balance disorder	1	2		3	
	Bradykinesia	0		0	1	
	Brain mass	0			1	
	Brain oedema	0	1	0	1	



			Goserelin			
Reaction SOC	Reaction PT	European Economic Area	Non European Economic Area	Not Specified	Total	
	Brain stem infarction	1	0		1	
	Burning sensation	1	0		1	
	Carpal tunnel syndrome Central pain syndrome	3	0		5 1	
	Cerebellar ataxia	0			1	
	Cerebellar syndrome	2	0		2	
	Cerebral atrophy	2	1		3	
	Cerebral haemorrhage	0	8		8	
	Cerebral infarction Cerebral ischaemia	0	13 1		13	
	Cerebrovascular accident	0	15		1 16	
	Cervicobrachial syndrome	0	1	0	1	
	Chorea	2	0		2	
	Cognitive disorder	2	0		2	
	Complex regional pain syndrome	0			1	
	Consciousness fluctuating Convulsion	0 2	3		<u>1</u> 5	
	Coordination abnormal	3	1		4	
	Dementia	0	2		2	
	Dementia Alzheimer's type	2	1		3	
	Demyelinating polyneuropathy	0	1		1	
	Demyelination Depressed level of consciousness	3	1 2		2	
	Diplegia	1	0		1	
	Disturbance in attention	2	2		4	
	Dizziness	13	17	0	30	
	Dysarthria	1	1		2	
	Dysgeusia	2	3		5	
	Dystonia Encephalitis	1 0	0		<u>1</u>	
	Encephalomyelitis	1	0		1	
	Encephalopathy	0	1		1	
	Epilepsy	3	0		3	
	Grand mal convulsion	0	1		2	
	Guillain-Barre syndrome Headache	23	2 40		2 63	
	Hemianopia heteronymous	0	1		1	
	Hemiparesis	0	1		1	
	Hepatic encephalopathy	2	2		4	
Nerv	Hydrocephalus	1	2		3	
	Hyperaesthesia Hypoaesthesia	0 4	1 6	0	1 10	
	Hypoglycaemic coma	0	1	0	10	
	Hypotonia	0	1	0	1	
	IIIrd nerve paralysis	0	1		1	
	Intracranial pressure increased	1	0		1	
	Intracranial venous sinus thrombosis Ischaemic stroke	0	2 1		2	
	Lethargy	0	2		2	
	Loss of consciousness	2	8	0	10	
	Memory impairment	3	0		3	
	Mental impairment	1	1		2	
	Migraine Monoplegia	1 0	2	0	3 2	
	Motor dysfunction	1	0		1	
	Multiple sclerosis	3	0		3	
	Multiple sclerosis relapse	1	0	0	1	
	Myasthenia gravis	2	0		2	
	Nervous system disorder	0			1	
	Neuralgia Neuroleptic malignant syndrome	0	1 1		<u>1</u>	
	Neuropathy peripheral	2	4		6	
	Optic neuritis	1	0		1	
	Paraesthesia	10	12		22	
	Paralysis	0			2	
	Paraplegia Parkingon's disease	2	1 1		2	
	Parkinson's disease Parkinsonism	2	0		3 2	
	Peripheral paralysis	0	1		1	
	Petit mal epilepsy	0			1	
	Polyneuropathy	3	3	0	6	
	Posterior reversible encephalopathy syndrome	0	1		1	
	Presyncope Restless legs syndrome	1	1		2 1	
	Restless legs syndrome	0	1	0	1	



			Goserelin			
Reaction SOC	Reaction PT	European Economic Area	Non European Economic Area	Not Specified	Total	
	Sciatica	Area 0	1	O O	1 otal	
	Sensory disturbance	0	1	0	1	
	Sensory loss	0	1 4	0	1 5	
	Somnolence Spinal cord compression	0	3	0	3	
	Spinal cord disorder	0	1	0	1	
	Subarachnoid haemorrhage	0	2	0	2	
	Superior sagittal sinus thrombosis	3	<u> </u>	0	3 6	
	Syncope Toxic encephalopathy	0	2	0	2	
	Toxic neuropathy	0	1	0	1	
	Transient ischaemic attack	0	4	0	4	
	Tremor Vascular dementia	1 2	0 1	0	1 3	
	VIIth nerve paralysis	0	1	0	1	
	Visual field defect	0	1	0	1	
	Abortion	1	0	0	1	
	Abortion missed Abortion spontaneous	1 1	0 4	0	1 5	
	Cervical incompetence	1	0	0	1	
	Foetal damage	1	0	0	1	
	Foetal death	0	1	0	1	
Preg	Foetal disorder	1	1	0	2 1	
	Polyhydramnios Pregnancy	0	1 0	0	1	
	Premature baby	0	2	0	2	
	Premature rupture of membranes	0	1	0	1	
	Premature separation of placenta	1 0	0 1	0	1 1	
	Unintended pregnancy Unwanted pregnancy	2	0	0	2	
	Abnormal behaviour	0	1	0	1	
	Adjustment disorder with depressed mood	0	1	0	1	
	Affect lability	1	0 1	0	1 1	
	Affective disorder Aggression	0 2	2	0	4	
	Agitation	1	3	0	4	
	Anger	0	2	0	2	
	Anorexia nervosa	0 3	1 7	0	1 10	
	Anxiety Anxiety disorder	0	1	0	10	
	Apathy	1	1	0	2	
	Bipolar disorder	0	1	0	1	
	Communication disorder Completed suicide	2	0	0	2	
	Confusional state	4	<u>2</u> 5	0	6 6	
	Delirium	0	1	0	1	
	Delusion	1	0	0	1	
	Delusional disorder, unspecified type	0	1	0	1	
	Depressed mood Depression		3 32	1 2	6 47	
	Disturbance in sexual arousal	1	0	0	1	
	Emotional disorder	0	1	0	1	
	Emotional distress Emotional poverty	1 1	1 0	0	2 1	
	Fear	0	2	0	2	
	Generalised anxiety disorder	0	1	0	1	
	Hallucination	0	1	0	1	
	Hallucination, auditory	2	0 1	0	2 2	
	Hostility Impatience	0	1	0	1	
	Impulsive behaviour	1	0	0	1	
Psych	Insomnia	4	26	2	32	
'	Intentional drug misuse Jealous delusion	0	<u>3</u>	0	3 1	
	Libido decreased	1	5	0	6	
	Libido increased	1	0	0	1	
	Loss of libido	0	3	0	3	
	Major depression Mania	0	1 2	0	1 2	
	Mental disorder	2	0	0	2	
	Middle insomnia	0	1	0	1	
	Mood altered	1	1	0	2	
	Mood swings	1	1	0	2	
	Nervousness	0	1	0	1	



		Goserelin			
Reaction SOC	Reaction PT	European Economic Area	Non European Economic Area	Not Specified	Total
	Nightmare	Alea 0		Specified 0	1
	Panic attack	2	0	0	2
	Panic disorder Panic reaction	0	2	0	2 1
	Paranoia	0	3	0	3
	Personality change	0	1	0	1
	Personality disorder Psychotic behaviour	1 1	0	0	1 1
	Psychotic disorder	6	6	0	12
	Restlessness	1	0	0	1
	Schizophrenia Slaan digardan	0 2		0	1
	Sleep disorder Somatoform disorder	0	0	0	2 1
	Stress	0	1	0	1
	Substance-induced psychotic disorder	0	1	0	1
	Suicidal behaviour Suicidal ideation	1 4	0 4	0	<u>1</u> 8
	Suicide attempt	0	3	0	3
	Thinking abnormal	0	1	0	1
	Withdrawal syndrome Azotaemia	2	1	0	3 2
	Azotaemia Bladder hypertrophy	0	1	0	1
	Bladder pain	0	3	0	3
	Calculus bladder	0		0	1
	Calculus urinary Chromaturia	0	2	0	<u>2</u> 5
	Contracted bladder	1	0	0	1
	Cystitis haemorrhagic	0	1	0	1
	Cystitis interstitial Dysuria	0	2 6	0	<u>2</u> 7
	Eosinophilic cystitis	1	0	0	1
	Haematuria	0	5	0	5
	Haemorrhage urinary tract	0		0	1 1
	Hydronephrosis Hypotonic urinary bladder	0		0	1
	Incontinence	0		0	1
	Micturition disorder	0	1	0	1
	Micturition urgency Nephritis	0	1	0	1 1
Renal	Nephrolithiasis	0	3	0	3
Kenai	Nephrotic syndrome	0	2	0	2
	Nocturia Oliguria	0	1	0	1
	Pollakiuria	2	2	0	4
	Polyuria	0		0	1
	Proteinuria Pvuria	1 0	0 2	0	<u>1</u>
	Renal colic	0		0	1
	Renal cyst	0		0	1
	Renal disorder Renal failure	0		0	3 9
	Renal failure acute	2	1	0	3
	Renal impairment	1	4	0	5
	Renal pain	0		0	2
	Ureteric obstruction Urethral disorder	0		0	2 2
	Urinary incontinence	2	3	0	5
	Urinary retention	1	5		6
	Urinary tract obstruction Urinary tract pain	2 0	1	0	3 1
	Amenorrhoea	5	13	0	18
	Breast disorder	2	0		2
	Breast enlargement Breast induration	0	3		3 1
	Breast pain	2	5	0	7
	Breast swelling	0	4		4
	Breast tenderness Dysfunctional uterine bleeding	1 0	0	0	1 1
	Dyspareunia Dispareunia	0		0	2
	Endometrial hyperplasia	0	3	0	3
	Endometrial hypoplasia	0		0	1 1
			. 11	. (1)	
	Endometriosis Erectile dysfunction	4			8



		Goserelin			
Reaction SOC	Reaction PT	European Economic Area	Non European Economic Area	Not Specified	Total
	Genital rash	Alea 0		Specified 0	1 otal
	Gynaecomastia	2	7	0	9
	Infertility female Menopausal symptoms	1 3	0	0	1 4
	Menorrhagia	1	1	0	2
	Menstrual disorder	0	4	0	4
	Metrorrhagia Nipple pain	2	4 1	0	6 1
	Ovarian atrophy	0		0	1
Repro	Ovarian cyst	4	2	0	6
	Ovarian disorder	1	1	0	2
	Ovarian enlargement Ovarian hyperstimulation syndrome	1 0	0 1	0	1
	Pelvic pain	0	1	0	1
	Penile pain	1	1	0	2
	Penile size reduced	1	0	0	1
	Penis disorder Polycystic ovaries	0	1 0	0	1
	Postmenopausal haemorrhage	0	1	0	1
	Priapism	0	2	0	2
	Prostatic disorder	0		0	1
	Prostatic haemorrhage	0	1	0	1
	Prostatitis Scrotal irritation	0		0	2 1
	Scrotal ulcer	1	0	0	1
	Testicular atrophy	3	0	0	3
	Testicular disorder	1	1	0	2
	Testicular pain Uterine haemorrhage	3	<u>1</u> 5	0	<u>4</u> 5
	Vaginal discharge	1	0	0	1
	Vaginal haemorrhage	4	17	0	21
	Vulval disorder	0	1	0	1
	Vulvovaginal dryness Acute pulmonary oedema	1	1 0	0	2 1
	Alveolitis fibrosing	1	0	0	1
	Asthma	3	5	0	8
	Atelectasis	0	1	0	1
	Bronchospasm Choking	1 0	1 1	0	2 1
	Chronic obstructive pulmonary disease	0	5	0	5
	Cough	2	5	1	8
	Dysphonia	0	2	0	2
	Dyspnoea Dyspnoea exertional	19	26 1	0	45
	Eosinophilic pneumonia	0	2	0	2
	Eosinophilic pneumonia acute	0		0	2
	Epistaxis	2	0	0	2
	Hyperventilation Hypoxia	2	1	0	3
	Interstitial lung disease	1	101	0	102
	Laryngeal oedema	0		0	2
	Laryngospasm	1	0	0	1
	Laryngotracheal oedema Lung disorder	0	1 2	0	3
Resp	Lung infiltration	1	1	0	2
	Nasal congestion	1	1	0	2
	Nasal mucosal disorder	0		0	1
	Neonatal respiratory distress syndrome Obstructive airways disorder	0	1 0	0	1 1
	Organising pneumonia	0		0	5
	Oropharyngeal pain	0	1	0	1
	Pharyngeal oedema	2	0	0	2
	Pleural effusion Pleurisy	1 2	6 0	0	7 2
	Pneumonitis	0	2	0	2
	Pneumothorax	0	1	0	1
	Productive cough	0		0	2
	Pulmonary alveolar haemorrhage	0	1 8	0	1 14
	Pulmonary embolism Pulmonary fibrosis	1	4	0	14 5
	Pulmonary infarction	0		0	3
	Pulmonary oedema	2	4	0	6
	Respiratory arrest	0		0	1
	Respiratory disorder	2	0	0	2



		Goserelin			
Reaction SOC	Reaction PT	European Economic Area	Non European Economic Area	Not Specified	Total
	Respiratory distress	0	1	_	1
	Respiratory failure	0			2
	Rhinorrhoea	1	2		3
	Sleep apnoea syndrome Sputum discoloured	0	1 1		1 1
	Sputum increased	0	2		2
	Stridor	0	1	0	1
	Suffocation feeling	1	0		1
	Tachypnoea Wheezing	0	1 2		<u>1</u> 3
	Acne	0	1		1
	Acute febrile neutrophilic dermatosis	1	0		1
	Acute generalised exanthematous pustulosis	1	0		1
	Alopecia	6			14
	Angioedema Blister	2	5 1		
	Cold sweat	0			1
	Cutaneous vasculitis	1	0		1
	Decubitus ulcer	0	1		1
	Dermatitis Dermatitie bullous	1	0		1
	Dermatitis bullous Dermatitis psoriasiform	1 0	1 1		2 1
	Dermatomyositis	1	1		2
	Drug eruption	1	5		6
	Dry skin	0	1		1
	Eczema Erythema	5 2	1		6
ı	Erythema multiforme	1	<u>3</u>		<u>6</u> 3
	Erythema nodosum	1	2		3
	Generalised erythema	0	2	0	2
	Granuloma annulare	1	0		1
	Haemorrhage subcutaneous Hair colour changes	0	2		2 1
	Hair growth abnormal	0	2		2
	Hair texture abnormal	0	1		1
	Hirsutism	0	1		1
	Hyperhidrosis	8	16		24
	Hypotrichosis Leukocytoclastic vasculitis	1 1	0		<u>1</u>
	Lipodystrophy acquired	1	0		1
	Madarosis	1	1	0	2
Skin	Nail discolouration	0			1
	Night sweats Onycholysis	3	0	0	5 1
	Palmar-plantar erythrodysaesthesia syndrome	1	0		1
	Papule	1	0		1
	Parapsoriasis	1	0		1
	Pemphigoid	1	1		2
	Photosensitivity reaction Pigmentation disorder	3 0	3 2	0	<u>6</u> 2
	Pityriasis rosea	0			1
	Pruritus	5	13		19
	Pruritus generalised	0			4
	Psoriasis	1	1		2
	Rash Rash erythematous	8 2	22		30 3
	Rash generalised	6	4		10
	Rash macular	2	0	0	2
	Rash maculo-papular	1	3		4
	Rash papular	1 0	1		2
	Rash pruritic Skin discolouration	2	<u>2</u> 6		2 8
	Skin disorder	0	1	0	1
	Skin erosion	0			1
	Skin fissures	1	0		1
	Skin reaction Stevens-Johnson syndrome	1 1	0		<u>1</u>
	Subcutaneous nodule	0	1		1
	Sweat gland disorder	1	0		1
	Swelling face	2	2	0	4
	Systemic lupus erythematosus rash	1	0		1
	Li evice el cin emination	1		0	_
	Toxic skin eruption Urticaria	7	<u>5</u>		6 14



Reaction SOC	Reaction PT		Goserelin			
		European Economic Area	Non European Economic Area	Not Specified	Total	
SocCi	Bedridden	Alea 0	Area 3	Specified 0	10tai 3	
	Walking aid user	0	1	0	1	
	Abdominal operation	0	2	0	2	
	Abortion induced	1	3	0	4	
	Breast reconstruction	0	1	0	1	
	Cardiac pacemaker insertion	1	0	0	1	
	Cerebrovascular operation	0	1	0	1	
	Chemotherapy	0	1	0	1	
	Debridement	0	1	0	1	
	Dental care	1	0	0	1	
	Haemodialysis	1	2	0	3	
	Hospitalisation	1	1	0	2	
Surg	Hysterectomy	0	1	0	1	
- · J	Medical device implantation	0	1	0	1	
	Nasal operation	0	1	0	1	
	Off label use	0	6	0	6	
	Oophorectomy	0	1	0	1	
	Radiotherapy to bone	0	1	0	1	
	Sequestrectomy	0	1	0	1	
	Skin graft	0	1	0	1	
	Surgery	0	2	0	2	
	Tooth extraction	1	0	0	1	
	Transfusion	0	1	0	1	
	Aneurysm ruptured	0	1	0	1	
	Angiopathy	0	1	0	1	
	Arterial stenosis	0	1	0	1	
	Arteritis	0	1	0	1	
	Blood pressure fluctuation	0	4	0	4	
	Circulatory collapse	1	0	0	1	
	Deep vein thrombosis	1	11	1	13	
	Embolism	0	2	0	2	
	Flushing	5	4	0	9	
	Haematoma	1	6	0	7	
	Haemorrhage	2	7	0	9	
	Haemorrhagic vasculitis	0	1	0	1	
	Hot flush	17	76	0	93	
	Hypertension	15	20	1	36	
	Hypertensive crisis	2	0	0	2	
	Hypoperfusion	1	0	0	1	
	Hypotension	4	6	0	10	
	Intra-abdominal haematoma	4	1	0	5	
Vasc	Jugular vein thrombosis	1	0	0	1	
	Labile blood pressure	1	0	0	1	
	Lymphoedema	2	0	0	2	
		1	0	0	1	
	Neovascularisation Orthograpis hypotonsion		2			
	Orthostatic hypotension	1 1		0	3 1	
	Pallor		0		1	
	Peripheral vascular disorder	0	1	0		
	Raynaud's phenomenon	1	0		1 1	
	Shock hapmarrhagis	0	1	0		
	Shock haemorrhagic	0	2	0	2	
	Thrombophlebitis	1	0	0	1	
	Thrombosis	0	2	0	2	
	Varicose vein	0	1	0	1	
	Vascular compression	1	0	0	1	
	Vasculitis	0	1	0	1	
	Vasospasm	0		1	1	
	Vena cava thrombosis	0		0	1	
	Venous thrombosis limb	0	1	0	1	