

Reaction SOC	Reaction PT	Histrelin		
		European Economic Area	Non European Economic Area	Total
Eye	Diplopia	0	1	1
Gastr	Nausea	0	1	1
	Periodontal disease	0	1	1
Genrl	Asthenia	0	1	1
	Complication of device removal	1	1	2
	Death	0	1	1
	Device expulsion	0	2	2
	Drug ineffective	1	19	20
	Fatigue	1	1	2
	Localised oedema	0	1	1
	Malaise	0	1	1
	Oedema peripheral	1	0	1
Product quality issue	0	2	2	
Hepat	Liver disorder	0	1	1
Immun	Drug hypersensitivity	0	1	1
Infec	Cellulitis	1	1	2
	Implant site infection	0	3	3
Inj&P	Drug administration error	0	1	1
	Drug dispensing error	0	1	1
Inv	Blood testosterone abnormal	0	1	1
	Blood testosterone increased	2	18	20
	Cardiac output decreased	0	2	2
	Prostatic specific antigen increased	1	2	3
	White blood cell count increased	0	1	1
Musc	Arthralgia	1	1	2
	Bone loss	0	1	1
	Myopathy	1	0	1
Neopl	Gastric cancer	0	1	1
	Lung neoplasm malignant	1	0	1
	Metastases to lung	0	1	1
	Prostate cancer metastatic	0	2	2
	Renal cancer	0	1	1
Nerv	Ataxia	0	1	1
	Basal ganglia haemorrhage	0	1	1
	Cerebral infarction	0	1	1
	Disturbance in attention	0	1	1
	Dizziness	0	1	1
	Headache	0	1	1
	Lethargy	0	1	1
Psych	Confusional state	0	1	1
	Depression	0	1	1
	Loss of libido	0	1	1
	Paranoia	0	1	1
Renal	Micturition urgency	0	1	1
	Nocturia	0	10	10
	Urinary hesitation	0	8	8
	Urinary retention	0	7	7
Repro	Erectile dysfunction	0	5	5
Resp	Dyspnoea	0	3	3
Skin	Rash pruritic	0	1	1
	Skin odour abnormal	0	1	1
Vasc	Hot flush	0	1	1
	Hypertension	0	1	1