

| 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     |