Pergosafe 0.5 mg film-coated tablets for horses

Authorised

- Pergolide mesilate

Product identification

Medicine name:
Pergosafe 0.5 mg film-coated tablets for horses

Active substance:
Pergolide mesilate

Target species:
Horse

Route of administration:
Oral use

Product details

Active substance and strength:
Pergolide mesilate
0.66 milligram(s) / 1.00 Tablet

Pharmaceutical form:
Film-coated tablet

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QN04BC02

Legal status of supply:
Veterinary medicinal product subject to veterinary prescription

Authorisation status:
Valid

Authorised in:
Norway

Package description:
OPA-aluminium-PVC-aluminium blisters, containing 10 tablets each, in a carton box (10 tablets)
OPA-aluminium-PVC-aluminium blisters, containing 10 tablets each, in a carton box (100 tablets)
PVC-PE-PVDC-aluminium blisters, containing 10 tablets each, in a carton box (60 tablets)
PVC-PE-PVDC-aluminium blisters, containing 10 tablets each, in a carton box (90 tablets)
PVC-PE-PVDC-aluminium blisters, containing 10 tablets each, in a carton box (240 tablets)
PVC-PE-PVDC-aluminium blisters, containing 10 tablets each, in a carton box (30 tablets)
OPA-aluminium-PVC-aluminium blisters, containing 10 tablets each, in a carton box (90 tablets)
PVC-PE-PVDC-aluminium blisters, containing 10 tablets each, in a carton box (120 tablets)
OPA-aluminium-PVC-aluminium blisters, containing 10 tablets each, in a carton box (30 tablets)
OPA-aluminium-PVC-aluminium blisters, containing 10 tablets each, in a carton box (60 tablets)
OPA-aluminium-PVC-aluminium blisters, containing 10 tablets each, in a carton box (240 tablets)
OPA-aluminium-PVC-aluminium blisters, containing 10 tablets each, in a carton box (120 tablets)

OPA-aluminium-PVC-aluminium blisters, containing 10 tablets each, in a carton box (160 tablets)
PVC-PE-PVDC-aluminium blisters, containing 10 tablets each, in a carton box (160 tablets)
PVC-PE-PVDC-aluminium blisters, containing 10 tablets each, in a carton box (10 tablets)
PVC-PE-PVDC-aluminium blisters, containing 10 tablets each, in a carton box (100 tablets)

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Hybrid application (Article 13(3) of Directive No 2001/82/EC)

Marketing authorisation holder:
Alfasan Nederland B.V.

Marketing authorisation date:
25/02/2022

Manufacturing sites for batch release:
Alfasan Nederland B.V.
Lelypharma B.V.

Responsible authority:
Norwegian Medical Products Agency

Authorisation number:
20-13606

Date of authorisation status change:
25/02/2022

Reference member state:
Netherlands

Procedure number:
NL/V/0357/001

Concerned member states:
Austria Belgium Bulgaria Croatia Cyprus Czechia Denmark Estonia Finland France Germany Greece Hungary Iceland Ireland Italy Latvia Lithuania Luxembourg Norway Poland Portugal Romania Slovakia Slovenia Spain Sweden United Kingdom (Northern Ireland)

To consult adverse reactions on veterinary medicinal products please go to www.adrreports.eu/vet

Documents

Combined File of all Documents

Package Leaflet

This document does not exist in this language (English). You can find it in another language below.

Summary of Product Characteristics

This document does not exist in this language (English). You can find it in another language below.