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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:
Germany

Package description:
PVC-PE-PVDC-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 (10 tablets)
PVC-PE-PVDC-aluminium blisters, containing 10 tablets each, in a carton box (160 tablets)
OPA-aluminium-PVC-aluminium blisters, containing 10 tablets each, in a carton box (160 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 (240 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 (30 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 (90 tablets)
PVC-PE-PVDC-aluminium blisters, containing 10 tablets each, in a carton box (30 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 (90 tablets)
PVC-PE-PVDC-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 (100 tablets)
OPA-aluminium-PVC-aluminium blisters, containing 10 tablets each, in a carton box (10 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:
24/08/2021

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

Responsible authority:
Federal Office Of Consumer Protection And Food Safety

Authorisation number:
V7001703.00.00

Date of authorisation status change:
24/08/2021

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)

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Documents

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