Apovomin 1 mg/ml solution for injection for dogs

Authorised

- Apomorphine hydrochloride hemihydrate

Product identification

Medicine name:
Apovomin 1 mg/ml solution for injection for dogs

Active substance:
Apomorphine hydrochloride hemihydrate

Target species:
Dog

Route of administration:
Subcutaneous use

Product details

Active substance and strength:
Apomorphine hydrochloride hemihydrate
1.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Solution for injection

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QN04BC07

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

Authorisation status:
Valid

Authorised in:
Iceland

Package description:
Clear Type I glass vials containing 5 ml, closed with a coated Type I bromobutyl rubber stopper and sealed with an aluminium cap. Each vial is packed into a cardboard box.

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Full application - Known active substance (Article 12(3) of Directive No 2001/82/EC)

Marketing authorisation holder:
Dechra Regulatory B.V.

Marketing authorisation date:
15/12/2020

Manufacturing sites for batch release:
Produlab Pharma B.V.

Responsible authority:
Icelandic Medicines Agency

Authorisation number:
IS/2/20/016/01

Date of authorisation status change:
15/12/2020

Reference member state:
Netherlands

Procedure number:
NL/V/0343/001

Concerned member states:
Austria Bulgaria Croatia Czechia Denmark Estonia Finland France Greece Hungary Iceland Ireland Italy Latvia Lithuania 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