Apovomin 3 mg/ml solution for injection for dogs

Authorised

• Apomorphine hydrochloride hemihydrate

Product identification

Medicine name:

Apovomin 3 mg/ml solution for injection for dogs Apovomin, 3mg/ml, Injekční roztok

Active substance:

Apomorphine hydrochloride hemihydrate

Target species:

Dog

Route of administration:

Subcutaneous use

Product details

Active substance and strength:

Apomorphine hydrochloride hemihydrate 3.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:

Solution for injection

Withdrawal period by route of administration:

Subcutaneous use:

. Dog

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QN04BC07

Legal status of supply:

This information is not available for this product.

Authorisation status:

Valid

Authorised in:

Czechia

Package description:

Clear Type I glass vial containing 10ml, closed with a coated bromobutyl rubber stopper and sealed with an aluminium cap. Each vial is packed into a cardboard box.

Pack size: Multi-pack with 10 vials of 10 ml

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

Pack size: Multi-pack with 10 vials of 5 ml

Clear Type I glass vial containing 20 ml, closed with a coated bromobutyl rubber stopper and sealed with an aluminium cap. Each vial is packed into a cardboard box.

Pack size: Box with 1 vial of 20 ml

Clear Type I glass vial containing 10ml, closed with a coated bromobutyl rubber stopper and sealed with an aluminium cap. Each vial is packed into a cardboard box.

Pack size: Box with 1 vial of 10 ml

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

Pack size: Box with 1 vial of 5 ml

Additional information

Entitlement type:

Marketing Authorisation

Legal basis of product authorisation:

Generic application (Article 13(1) of Directive No 2001/82/EC)

Marketing authorisation holder:

Dechra Regulatory B.V.

Marketing authorisation date:

16/01/2019

Manufacturing sites for batch release:

Produlab Pharma B.V.

Responsible authority:

USKVBL

Authorisation number:

96/005/19-C

Date of authorisation status change:

16/01/2019

Reference member state:

Ireland

Procedure number:

IE/V/0482/001

Concerned member states:

Austria Belgium Bulgaria Croatia Cyprus Czechia Denmark Estonia Finland France Germany Greece Hungary Iceland Italy Latvia Lithuania Luxembourg Netherlands 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

Summary of Product Characteristics

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Package Leaflet

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

Labelling

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