DOMOSEDAN GEL 7.6 mg/ml oromucosal gel

Authorised

- DETOMIDINE HYDROCHLORIDE FOR VETERINARY USE

Product identification

Medicine name:
DOMOSEDAN GEL 7.6 mg/ml oromucosal gel

Active substance:
DETOMIDINE HYDROCHLORIDE FOR VETERINARY USE

Target species:
Horse

Route of administration:
Sublingual use

Product details

Active substance and strength:
DETOMIDINE HYDROCHLORIDE FOR VETERINARY USE
7.60 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Oromucosal gel

Withdrawal period by route of administration:

Sublingual use:

- **Horse**
  - Meat and offal. 0 day
  - Milk. 0 hour

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QN05CM90

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

Authorisation status:
Valid

Authorised in:
Slovenia

Available in:
Slovenia

Package description:
Pre-filled, single-dose syringe enabling doses from 1.0 ml to 3.0 ml packed in outer carton. Pre-filled syringes consistof a syringe barrel (HDPE), cap (LDPE), plunger (HDPE) and a locking ring.Package sizes: 1 x 3.0 ml (1 syringe per carton)

Additional information

Entitlement type:
Marketing Authorisation

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

Marketing authorisation holder:
Orion Corporation

Marketing authorisation date:
7/04/2009

Manufacturing sites for batch release:
Orion Corporation

Responsible authority:
Agency For Medicinal Products And Medical Devices Of The Republic Of Slovenia

Authorisation number:
DC/V/0094/002

Date of authorisation status change:
7/04/2009

Reference member state:
Ireland

Procedure number:
IE/V/0218/001

Concerned member states:
Austria Belgium Bulgaria 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

English (PDF)

Published on: 4/05/2025
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Package Leaflet

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Labelling

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Combined File of all Documents