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Rominervin 10 mg/ml Solution for Injection for Horses

Authorised

- Romifidine hydrochloride

Product identification

Medicine name:
Rominervin 10 mg/ml Solution for Injection for Horses

Active substance:
Romifidine hydrochloride

Target species:
Horse

Route of administration:
Intravenous use

Product details

Active substance and strength:
Romifidine hydrochloride
10.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Solution for injection

Withdrawal period by route of administration:

Intravenous use:

- **Horse**
  - Meat and offal. 6 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QN05CM93

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

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Authorisation status:

Valid

Authorised in:

Sweden

Available in:

Sweden

Package description:

Multi-pack with 10 boxes each containing 1 vial of 20 ml. Colourless type I glass vials closed with a coated bromobutyl rubber stopper and aluminium cap. One glass vial in a cardboard box.
Multi-pack with 10 boxes each containing 1 vial of 50 ml. Colourless type I glass vials closed with a coated bromobutyl rubber stopper and aluminium cap. One glass vial in a cardboard box.
Box with 1 vial 10 ml. Colourless type I glass vials closed with a coated bromobutyl rubber stopper and aluminium cap. One glass vial in a cardboard box.
Box with 1 vial of 20 ml. Colourless type I glass vials closed with a coated bromobutyl rubber stopper and aluminium cap. One glass vial in a cardboard box.
Box with 1 vial of 50 ml. Colourless type I glass vials closed with a coated bromobutyl rubber stopper and aluminium cap. One glass vial in a cardboard box.
Multi-pack with 10 boxes each containing 1 vial of 10 ml. Colourless type I glass vials closed with a coated bromobutyl rubber stopper and aluminium cap. One glass vial in a cardboard box.

Multi-pack with 6 boxes each containing 1 vial of 10 ml. Colourless type I glass vials closed with a coated bromobutyl rubber stopper and aluminium cap. One glass vial in a cardboard box.
Multi-pack with 6 boxes each containing 1 vial of 20 ml. Colourless type I glass vials closed with a coated bromobutyl rubber stopper and aluminium cap. One glass vial in a cardboard box.
Multi-pack with 6 boxes each containing 1 vial of 50 ml. Colourless type I glass vials closed with a coated bromobutyl rubber stopper and aluminium cap. One glass vial in a cardboard box.

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:
Le Vet. Beheer B.V.

Marketing authorisation date:
12/10/2018

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

Responsible authority:
Swedish Medical Products Agency

Authorisation number:
56830

Date of authorisation status change:
12/10/2018

Reference member state:
Netherlands

Procedure number:
NL/V/0318/001

Concerned member states:
Austria Belgium Bulgaria Croatia Czechia Denmark Estonia Finland France Germany 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

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.

Combined File of all Documents

Labelling

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

Rominervin PuAR.pdf