

# 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

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**Active substance:**

Romifidine hydrochloride

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**Target species:**

Horse

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**Route of administration:**

Intravenous use

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## Product details

**Active substance and strength:**

Romifidine hydrochloride  
10.00 milligram(s) / 1.00 millilitre(s)

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**Pharmaceutical form:**

Solution for injection

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**Withdrawal period by route of administration:****Intravenous use:**

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**Horse**

- Meat and offal. 6 day

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**Anatomical therapeutic chemical veterinary (ATCvet) codes:**

QN05CM93

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**Legal status of supply:**

Veterinary medicinal product subject to veterinary prescription

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**Authorisation status:**

Valid

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**Authorised in:**

Germany

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**Available in:**

Germany

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**Package description:**

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.

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 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 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.

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.

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 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 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.

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.

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## Additional information

**Entitlement type:**

Marketing Authorisation

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**Legal basis of product authorisation:**

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

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**Marketing authorisation holder:**

Le Vet. Beheer B.V.

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**Marketing authorisation date:**

8/01/2019

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**Manufacturing sites for batch release:**

Produlab Pharma B.V.

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**Responsible authority:**

Federal Office Of Consumer Protection And Food Safety

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**Authorisation number:**

402464.00.00

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**Date of authorisation status change:**

8/01/2019

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**Reference member state:**

Netherlands

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**Procedure number:**

NL/V/0318/001

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**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)

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To consult adverse reactions on veterinary medicinal products please go to  
[www.adrreports.eu/vet](http://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.