

# 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  
Rominervin 10 mg/ml Injektionslösung für Pferde

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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:****• 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:**

Austria

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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:**

30/01/2019

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**Manufacturing sites for batch release:**

Produlab Pharma B.V.

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**Responsible authority:**

Austrian Agency For Health And Food Safety

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**Authorisation number:**

838648

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**Date of authorisation status change:**

30/01/2019

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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.

### Labelling

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

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