# Dormazolam 5 mg/ml solution for injection for horses

Authorised

- Midazolam

## Product identification

**Medicine name:**
Dormazolam 5 mg/ml solution for injection for horses
Dormazolam 5 mg/ml raztopina za injiciranje za konje

**Active substance:**
Midazolam

**Target species:**
Horse

**Route of administration:**
Intravenous use

## Product details

**Active substance and strength:**
Midazolam
5.00 milligram(s) / 1.00 millilitre(s)

**Pharmaceutical form:**
Solution for injection

**Anatomical therapeutic chemical veterinary (ATCvet) codes:**
QN05CD08

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

**Authorisation status:**
Valid

**Authorised in:**
Slovenia

**Package description:**
Colourless type I glass vials of 50 ml closed with a coated bromobutyl rubber stopper and aluminium cap in a carton box.
Colourless type I glass vials of 20 ml closed with a coated bromobutyl rubber stopper and aluminium cap in a carton box.
Colourless type I glass vials of 10 ml closed with a coated bromobutyl rubber stopper and aluminium cap in a carton box.
Colourless type I glass vials of 5 ml closed with a coated bromobutyl rubber stopper and aluminium cap in a carton box.

## 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:**
Le Vet. Beheer B.V.

**Marketing authorisation date:**
9/08/2018

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

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

**Authorisation number:**
MR/V/0634/001

**Date of authorisation status change:**
9/08/2018

**Reference member state:**
Portugal

**Procedure number:**
PT/V/0138/001

**Concerned member states:**
Austria Belgium Croatia Czechia Denmark Estonia Finland France Germany Hungary Iceland Ireland Italy Latvia Lithuania Luxembourg Netherlands Norway Poland 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

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.

Package Leaflet

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

Combined File of all Documents