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Dormazolam 5 mg/ml solution for injection for horses

Authorised

- Midazolam

Product identification

Medicine name:
Dormazolam 5 mg/ml solution for injection for horses

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:
Belgium

Available in:
Belgium

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:
Dechra Regulatory B.V.

Marketing authorisation date:
5/10/2018

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

Responsible authority:
Federal Agency For Medicines And Health Products

Authorisation number:
BE-V534862

Date of authorisation status change:
5/10/2018

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.

Package Leaflet

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.

Combined File of all Documents