Presedine 10 mg/ml solution for injection for horses and cattle

Authorised

- Dexmedetomidine hydrochloride

Product identification

Medicine name:
Presedine 10 mg/ml solution for injection for horses and cattle
Presedine 10 mg/ml Injektionslösung für Pferde und Rinder

Active substance:
Dexmedetomidine hydrochloride

Target species:
Horse
Cattle

Route of administration:
Intramuscular use
Intravenous use

Product details

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

Pharmaceutical form:
Solution for injection

Withdrawal period by route of administration:

Intramuscular use:

- **Horse**
  - Meat and offal. 2 day
- **Cattle**
  - Meat and offal. 2 day
  - Milk. 12 hour

Intravenous use:

- **Horse**
  - Meat and offal. 2 day
- **Cattle**
  - Meat and offal. 2 day
  - Milk. 12 hour

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QN05CM90

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

Authorisation status:
Valid

Authorised in:
Austria

Package description:

Cardboard box with one type I clear glass vial containing 20 mL of product (in a 20 mL sized vial), with coated grey bromobutyl rubber stopper and aluminium cap. Cardboard box with one type I clear glass vial containing 10 mL of product (in a 10 mL sized vial) with coated grey bromobutyl rubber stopper and aluminium cap. Cardboard box with one type I clear glass vial containing 5 mL of product (in a 10 mL sized vial) with coated grey bromobutyl rubber stopper and aluminium cap.

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Generic application (Article 18 of Regulation (EU) 2019/6)

Marketing authorisation holder:
Alfasan Nederland B.V.

Marketing authorisation date:
31/07/2023

Manufacturing sites for batch release:
Alfasan Nederland B.V.

Responsible authority:
Austrian Agency For Health And Food Safety

Authorisation number:
841758

Date of authorisation status change:
31/07/2023

Reference member state:
Netherlands

Procedure number:
NL/V/0385/001

Concerned member states:
Austria Belgium Bulgaria Croatia Cyprus Czechia Denmark Estonia Finland France Germany Greece Hungary Iceland Ireland Italy Latvia Lithuania Luxembourg Norway Poland Portugal Romania Slovakia Slovenia Spain Sweden United Kingdom (Northern Ireland)

Generic of:
600000066141

To consult adverse reactions on veterinary medicinal products please go to www.adrreports.eu/vet

Documents

Combined File of all 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.