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Cepesedan RP 10 mg/ml, Solution for Injection for Horses and Cattle

Authorised

- DETOMIDINE HYDROCHLORIDE FOR VETERINARY USE

Product identification

Medicine name:
Cepesedan RP 10 mg/ml, Solution for Injection for Horses and Cattle

Active substance:
DETOMIDINE HYDROCHLORIDE FOR VETERINARY USE

Target species:
Cattle
Horse

Route of administration:
Intramuscular use
Intravenous use

Product details

Active substance and strength:
DETOMIDINE HYDROCHLORIDE FOR VETERINARY USE
10.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:

Solution for injection

Withdrawal period by route of administration:

Intramuscular use:

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

Intravenous use:

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

Norway

Available in:
Norway

Package description:
(ID4) 100 millilitre(s): unspecified outer container with 5 Vial (Glass) each with 20 millilitre(s), closed with Cap (Aluminium) and Stopper (Bromobutyl Rubber)
(ID3) 25 millilitre(s): unspecified outer container with 5 Vial (Glass) each with 5 millilitre(s), closed with Cap (Aluminium) and Stopper (Bromobutyl Rubber)
(ID2) 20 millilitre(s): unspecified outer container with 1 Vial (Glass) with 20 millilitre(s), closed with Cap (Aluminium) and Stopper (Bromobutyl Rubber)
(ID1) 5 millilitre(s): unspecified outer container with 1 Vial (Glass) with 5 millilitre(s), closed with Cap (Aluminium) and Stopper (Bromobutyl Rubber)

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Generic application (Article 13(1) of Directive No 2001/82/EC)

Marketing authorisation holder:
CP-Pharma Handelsgesellschaft mbH

Marketing authorisation date:
3/05/2007

Manufacturing sites for batch release:
CP-Pharma Handelsgesellschaft mbH

Responsible authority:
Norwegian Medical Products Agency

Authorisation number:
06-4551

Date of authorisation status change:
21/03/2010

Reference member state:
Germany

Procedure number:
DE/V/0117/001

Concerned member states:
Austria Belgium Czechia Denmark Finland France Hungary Ireland Italy Latvia Lithuania Netherlands Norway Poland Portugal Slovakia 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.

Combined File of all Documents

2400798-paren-20070604.pdf