Detonervin 10 mg/ml, solution for injection for horses and cattle

Authorised

DETOMIDINE HYDROCHLORIDE FOR VETERINARY USE

Product identification

Medicine name:

Detonervin 10 mg/ml, solution for injection for horses and cattle DETONERVIN 10 mg/ml SOLUCION INYECTABLE PARA CABALLOS Y BOVINO

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

Intravenous use:

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

Anatomical therapeutic chemical veterinary (ATCvet) codes:

ON05CM90

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Spain

Package description:

Clear colourless glass (type I) vials closed with a coated bromobutyl rubber stopper (type I) and an aluminium cap with a polypropylene lid. 5×1 glass vials with 20 ml. Clear colourless glass (type I) vials closed with a coated bromobutyl rubber stopper (type I) and an aluminium cap with a polypropylene lid. 5×1 glass vial with 5 ml. Clear colourless glass (type I) vials closed with a coated bromobutyl rubber stopper (type I) and an aluminium cap with a polypropylene lid. 1×1 glass vial with 5 ml. Clear colourless glass (type I) vials closed with a coated bromobutyl rubber stopper (type I) and an aluminium cap with a polypropylene lid. 1×1 glass vial with 20 ml.

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:

Le Vet. B.V.

Marketing authorisation date:

7/02/2011

Manufacturing sites for batch release:

Produlab Pharma B.V.

Responsible authority:

The Spanish Agency Of Medicines And Medical Devices

Authorisation number:

2252 ESP

Date of authorisation status change:

7/03/2019

Reference member state:

Netherlands

Procedure number:

NL/V/0147/001

Concerned member states:

Austria Belgium Czechia Denmark Finland France Greece Hungary Iceland Ireland Italy Luxembourg 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

English (PDF)

Published on: 16/06/2022

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Package Leaflet

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Labelling

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