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Xylasol 100 mg/ml, solution for injection for cattle and horses

Authorised

Xylazine hydrochloride

Product identification

Medicine name:

Xylasol 100 mg/ml, solution for injection for cattle and horses
XYLASOL 100 mg/ml SOLUCION INYECTABLE PARA BOVINO Y CABALLOS

Active substance:

Xylazine hydrochloride

Target species:

Cattle

Horse

Dog

Cat

Route of administration:

Intramuscular use

Intravenous use

Product details

Active substance and strength:

Xylazine hydrochloride

Pharmaceutical form:

Solution for injection

Withdrawal period by route of administration: Intramuscular use:

Cattle

- Milk. no withdrawal period 0 hours
- Meat and offal. 1 day

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Horse

- Milk. no withdrawal period 0 hours
- Meat and offal. 1 day

Intravenous use:

•

Cattle

- Milk. no withdrawal period 0 hours
- Meat and offal. 1 day

•

Horse

- Milk. no withdrawal period 0 hours
- Meat and offal. 1 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:

ON05CM92

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Authorised in:

Spain

Package description:

Cardboard box containing 1 vial (uncoloured glass type II, closed with bromobutyl rubber stopper, secured with aluminium cap) filled with 25 ml Cardboard box containing 1 vial (uncoloured glass type II, closed with bromobutyl rubber stopper, secured with aluminium cap) filled with 10 ml Cardboard box containing 1 vial (uncoloured glass type II, closed with bromobutyl rubber stopper, secured with aluminium cap) filled with 50 ml

Additional information

Entitlement type:

Marketing Authorisation

Legal basis of product authorisation:

Hybrid application (Article 13(3) of Directive No 2001/82/EC)

Marketing authorisation holder:

CP-Pharma Handelsgesellschaft mbH

Marketing authorisation date:

11/06/2012

Manufacturing sites for batch release:

CP-Pharma Handelsgesellschaft mbH

Responsible authority:

Spanish Agency Of Medicines And Medical Devices

Authorisation number:

2559 ESP

Date of authorisation status change:

1/01/2023

Reference member state:

Netherlands
Procedure number: NL/V/0158/002
Concerned member states: Germany Hungary Spain
To consult adverse reactions on veterinary medicinal products please go to www.adrreports.eu/vet
Documents
Combined File of all Documents
Summary of Product Characteristics
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Package Leaflet
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