Source URL: https://medicines.health.europa.eu/veterinary/en/60000036619

Xylasol 20 mg/ml, solution for injection for cattle, horses, dogs and cats

Authorised

• Xylazine hydrochloride

Product identification

Medicine name:

Xylasol 20 mg/ml, solution for injection for cattle, horses, dogs and cats Xysol vet. 20 mg/ml injeksjonsvæske, oppløsning til storfe, hest, hund og katt

Active substance:

Xylazine hydrochloride

Target species:

Cattle

Horse

Dog

Cat

Route of administration:

Intramuscular use

Intravenous use

Subcutaneous use

Product details

Active substance and strength:

Xylazine hydrochloride 23.31 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:

Solution for injection

Withdrawal period by route of administration: Intramuscular use:

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Cattle

- Milk. no withdrawal period Should be 0 days
- Meat and offal. 1 day

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Horse

- Milk. no withdrawal period Should be 0 days
- Meat and offal. 1 day

Intravenous use:

•

Cattle

- Milk. no withdrawal period Should be 0 days
- Meat and offal. 1 day

•

Horse

- Milk. no withdrawal period Should be 0 days
- Meat and offal. 1 day

Subcutaneous use:

Cattle

- Milk. no withdrawal period Should be 0 days
- Meat and offal. 1 day

Horse

- Milk. no withdrawal period Should be 0 days
- 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:

Valid

Authorised in:

Norway

Available in:

Norway

Package description:

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

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:

22/05/2012

Manufacturing sites for batch release:

CP-Pharma Handelsgesellschaft mbH

Responsible authority:

Norwegian Medical Products Agency

Authorisation number:

10-8082

Date of authorisation status change:

22/02/2017

Reference member state:

Netherlands

Procedure number:

NL/V/0158/001

Concerned member states:

Austria Denmark Finland France Germany Hungary Norway Spain Sweden

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



Combined File of all Documents

Summary of Product Characteristics

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