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

Authorised

- Xylazine hydrochloride

Product identification

Medicine name:
Xyla, 20 mg/ml solution for injection for cattle, horses, dogs and cats
Sedachem 20 mg/ml Oplossing voor injectie
Sedachem 20 mg/ml Solution injectable
Sedachem 20 mg/ml Injektionslösung

Active substance:
Xylazine hydrochloride

Target species:
Cattle
Horse
Dog
Cat

Route of administration:
Intravenous use
Intramuscular use
Subcutaneous use

Product details

Active substance and strength:
Xylazine hydrochloride
23.32 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Solution for injection

Withdrawal period by route of administration:
Intravenous use:

- **Cattle**
  - Meat and offal. 1 day
  - Milk. 0 hour
- **Horse**
  - Meat and offal. 1 day
  - Milk. 0 hour
- **Dog**

Intramuscular use:

- **Cattle**
  - Meat and offal. 1 day
  - Milk. 0 hour
- **Dog**
- **Cat**

Subcutaneous use:

-

Cat

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QN05CM92

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

Authorisation status:
Valid

Authorised in:
Belgium

Package description:
50 ml clear, type II glass bottle, closed with a bromobutyl rubber stopper and secured with an aluminium cap. Package size: 5x50 ml in a cardboard box.
50 ml clear, type II glass bottle, closed with a bromobutyl rubber stopper and secured with an aluminium cap. Package size: 1x50 ml in a cardboard box.

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:
Interchemie Werken De Adelaar Eesti AS

Marketing authorisation date:
16/11/2020

Manufacturing sites for batch release:
Interchemie Werken De Adelaar Eesti AS

Responsible authority:
Federal Agency For Medicines And Health Products

Authorisation number:
BE-V574533

Date of authorisation status change:
16/11/2020

Reference member state:
Estonia

Procedure number:
EE/V/0105/001

Concerned member states:
Austria Belgium Bulgaria Croatia Cyprus Czechia Denmark Finland France Germany Greece Hungary Iceland Ireland Italy Latvia Malta Netherlands Norway Poland Portugal Romania Slovakia Slovenia Spain Sweden

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.

Labelling

This document does not exist in this language (English). You can find it in another language below.
