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

Authorised

- Xylazine

Product identification

Medicine name:
Xylexx 20 mg/ml solution for injection for cattle, horses, dogs and cats
Xylexx Vet 20 mg/ml Stungulyf, lausn handa hestum, nautgripum, hundum og köttum

Active substance:
Xylazine

Target species:
Cat
Cattle
Dog
Horse

Route of administration:
Subcutaneous use
Intramuscular use
Intravenous use

Product details

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

Pharmaceutical form:
Solution for injection

Withdrawal period by route of administration:

Intramuscular use:

- **Cattle**
  - Meat and offal. 1 day — 1 day

Intravenous use:

- **Horse**
  - Meat and offal. 1 day — 1 day

- **Cattle**
  - Meat and offal. 1 day — 1 day
  - Milk. no withdrawal period — zero hours

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QN05CM92

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

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Authorisation status:
Valid

Authorised in:
Iceland

Package description:
Cardboard box containing 1 vial of 30 ml
Cardboard box containing 5 vials of 30 ml
Polystyrene box containing 24 vials of 30 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:
Alfasan Nederland B.V.

Marketing authorisation date:
7/02/2023

Manufacturing sites for batch release:
Alfasan Nederland B.V.

Responsible authority:
Icelandic Medicines Agency

Authorisation number:
IS/2/23/004/01

Date of authorisation status change:
7/02/2023

Reference member state:
Netherlands

Procedure number:
NL/V/0366/001

Concerned member states:
Austria Belgium Bulgaria Croatia Cyprus Czechia Denmark Estonia Finland France Germany Greece Hungary Iceland Ireland Italy Latvia Lithuania Luxembourg Norway Poland Portugal Romania Slovakia Slovenia Spain Sweden United Kingdom (Northern Ireland)

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

Documents

Combined File of all Documents

Labelling

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.

Summary of Product Characteristics

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