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 20 mg/ml solutione iniettabile per bovini, cavalli, cani e gatti

Active substance:

Xylazine

Target species:

Cat

Cattle

Dog

Horse

Route of administration:

Subcutaneous use Intramuscular use Intravenous use

Product details

Active substance and strength:

20.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:

Solution for injection

Withdrawal period by route of administration:

Subcutaneous use:

. Cat

Intramuscular use:

- . Cattle
 - Meat and offal. 1 day 1 day
- . Dog
- . Cat

Intravenous use:

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

Anatomical therapeutic chemical veterinary (ATCvet) codes:

ON05CM92

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Italy

Package description:

Clear type II glass vials containing 30 ml product, closed with a bromobutyl rubber stopper and aluminium cap in a polystyrene box.

Clear type II glass vials containing 30 ml product, closed with a bromobutyl rubber stopper and aluminium cap in a cardboard box

Clear type II glass vials containing 30 ml product, closed with a bromobutyl rubber stopper and aluminium cap in a cardboard or polystyrene 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:

Alfasan Nederland B.V.

Marketing authorisation date:

25/01/2023

Manufacturing sites for batch release:

Alfasan Nederland B.V.

Responsible authority:

Ministry Of Health

Authorisation number:

105633

Date of authorisation status change:

25/01/2023

Reference member state:

Netherlands

Procedure number:

NL/V/0366/001/DC

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

English (PDF)

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