Kaltetan, 250 mg/ml + 80 mg/ml + 10 mg/ml solution for infusion for horses, cattle and pigs

Authorised

- CALCIUM GLUCONATE FOR INJECTION
- Magnesium chloride hexahydrate
- Sodium glycerophosphate pentahydrate

Product identification

Medicine name:

Kaltetan, 250 mg/ml + 80 mg/ml + 10 mg/ml solution for infusion for horses, cattle and pigs Kaltetan, 250+80+10mg/ml, Injekční roztok

Active substance:

CALCIUM GLUCONATE FOR INJECTION Magnesium chloride hexahydrate Sodium glycerophosphate pentahydrate

Target species:

Horse Pig Cattle

Route of administration:

Intravenous use

Product details

Active substance and strength:

CALCIUM GLUCONATE FOR INIECTION 250.00 milligram(s)/millilitre / 1.00 milligram(s)/millilitre Magnesium chloride hexahydrate 80.00 milligram(s) / 1.00 millilitre(s) Sodium glycerophosphate pentahydrate 10.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:

Solution for infusion

Withdrawal period by route of administration: Intravenous use:

Horse

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- Milk. 5 week Meat and offal: Zero days. Milk: Zero hours

Piq

- Meat and offal. 5 week Meat and offal: Zero days

Cattle

- - Milk. 5 week Meat and offal: Zero days. Milk: Zero hours

Anatomical therapeutic chemical veterinary (ATCvet) codes:

OA12AX

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Czechia

Available in:

Czechia

Package description:

Polypropylene (PP) bottles closed with a bromobutyl rubber stopper, type I and secured with an aluminium cap. Package size: 500 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:

Vet-Agro Multi-Trade Company Sp. z o.o.

Marketing authorisation date:

14/02/2022

Manufacturing sites for batch release:

Przedsiebiorstwo Wielobranzowe Vet-Agro Sp. z o.o.

Responsible authority:

Institute For State Control Of Veterinary Biologicals And Medicaments

Authorisation number: 96/002/22-C

Date of authorisation status change: 14/02/2022

Reference member state:

Poland

Procedure number: PL/V/0110/001

Concerned member states:

Bulgaria Czechia Greece Hungary Italy Lithuania Portugal Romania Spain

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

Documents

Summary of Product Characteristics

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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.

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