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Kaltetan forte, 458.4 mg/ml + 125 mg/ml + 20 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 forte, 458.4 mg/ml + 125 mg/ml + 20 mg/ml solution for infusion for horses, cattle and pigs

Active substance:
CALCIUM GLUCONATE FOR INJECTION

Magnesium chloride hexahydrate

Sodium glycerophosphate pentahydrate

Target species:
Horse
Cattle
Pig

Route of administration:
Intravenous use

Product details

Active substance and strength:
CALCIUM GLUCONATE FOR INJECTION
458.40 milligram(s) / 1.00 millilitre(s)

Magnesium chloride hexahydrate
125.00 milligram(s) / 1.00 millilitre(s)

Sodium glycerophosphate pentahydrate
20.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Solution for infusion

Withdrawal period by route of administration:
Intravenous use:

- **Horse**
  - Milk. 0 week — Meat and offal: Zero days. Milk: Zero hours
- **Cattle**
  - Meat and offal. 0 week — Meat and offal: Zero days. Milk: Zero hours
- **Pig**
  - Meat and offal. 0 week — Meat and offal: Zero days

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QA12AX

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

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Authorisation status:
Valid

Authorised in:
Greece

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

Marketing authorisation date:
3/04/2022

Manufacturing sites for batch release:
Przedsiebiorstwo Wielobranzowe Vet-Agro Sp. z o.o.

Responsible authority:
National Organization For Medicines

Authorisation number:
34227/04-04-2022/K-0248502

Date of authorisation status change:
3/04/2022

Reference member state:
Poland

Procedure number:
PL/V/0110/002

Concerned member states:
Bulgaria Czechia Greece Hungary Italy Lithuania Portugal Romania Spain

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

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.

Combined File of all Documents