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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:
Spain

Available in:
Spain

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:
2/06/2022

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

Responsible authority:
Spanish Agency Of Medicines And Medical Devices

Authorisation number:
4092 ESP

Date of authorisation status change:
3/06/2022

Reference member state:
Poland

Procedure number:

PL/V/0110/002

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

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.

Labelling

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

Combined File of all Documents