Addimag 240 mg/ml + 126 mg/ml solution for infusion for cattle

Authorised

- Magnesium chloride hexahydrate
- Calcium gluconate monohydrate

Product identification

Medicine name:
Addimag 240 mg/ml + 126 mg/ml solution for infusion for cattle

Active substance:
Magnesium chloride hexahydrate

Calcium gluconate monohydrate

Target species:
Cattle

Route of administration:
Intravenous use

Product details

Active substance and strength:
Magnesium chloride hexahydrate
126.00 milligram(s) / 1.00 millilitre(s)

Calcium gluconate monohydrate

240.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Solution for infusion

Withdrawal period by route of administration:
Intravenous use:

- **Cattle**
  - Meat and offal. no withdrawal period zero days
  - Milk. no withdrawal period zero hours

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QA12AX

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

Authorisation status:
Valid

Authorised in:
Luxembourg

Package description:
500 ml square shaped clear polypropylene (PP) bottle with a bromobutyl rubber stopper and an aluminium screw cap
750 ml square shaped clear polypropylene (PP) bottle with a bromobutyl rubber stopper and an aluminium screw cap.

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:

Hybrid application – change in strength (Article 19(1)(a) of Regulation (EU) 2019/6)

Marketing authorisation holder:
Alfasan Nederland B.V.

Marketing authorisation date:
22/12/2021

Manufacturing sites for batch release:
Alfasan Nederland B.V.
Bela-Pharm GmbH & Co. KG

Responsible authority:
Ministry Of Health And Social Security

Authorisation number:
V 004/04/03/2023

Date of authorisation status change:
3/03/2023

Reference member state:
Netherlands

Procedure number:
NL/V/0352/002

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

Labelling

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Combined File of all Documents

NLV0352001-002_Addimag _PuAR final.pdf