Butasal-100, 100 mg/ml + 0.05 mg/ml solution for injection for horses, cattle and dogs

Authorised

- Cyanocobalamin
- Butafosfan

Product identification

Medicine name:
Butasal-100, 100 mg/ml + 0.05 mg/ml solution for injection for horses, cattle and dogs

Active substance:
Cyanocobalamin
Butafosfan

Target species:
Cattle
Horse
Dog

Route of administration:
Intravenous use
Intramuscular use
Subcutaneous use

Product details

Active substance and strength:
Cyanocobalamin
0.05 milligram(s) / 1.00 millilitre(s)

Butafosfan
100.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Solution for injection

Withdrawal period by route of administration:
Intravenous use:

- **Cattle**
  - Meat and offal. 0 day
  - Milk. 0 hour
- **Horse**
  - Meat and offal. 0 day
  - Milk. 0 hour

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QA12CX99

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

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Authorisation status:
Valid

Authorised in:
Belgium

Package description:

Amber glass vial, closed with a bromobutyl rubber stopper and secured with an aluminium cap or flipoff cap with polypropylene cover. Package size: Cardboard box of 6 carton boxes of 1 vial of 100 mL
Amber glass vial, closed with a bromobutyl rubber stopper and secured with an aluminium cap or flipoff cap with polypropylene cover. Package size: Cardboard box of 1 vial of 100 mL.
Amber glass vial, closed with a bromobutyl rubber stopper and secured with an aluminium cap or flip-off cap with polypropylene cover. Cardboard box of 6 carton boxes of 1 vial of 50 mL.
Amber glass vial, closed with a bromobutyl rubber stopper and secured with an aluminium cap or flip-off cap with polypropylene cover. Cardboard boxes of 1 vial of 50 mL.

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:
Interchemie Werken De Adelaar Eesti AS

Marketing authorisation date:
13/07/2021

Manufacturing sites for batch release:
Interchemie Werken De Adelaar Eesti AS

Responsible authority:
Federal Agency For Medicines And Health Products

Authorisation number:
BE-V587537

Date of authorisation status change:
13/07/2021

Reference member state:
Estonia

Procedure number:
EE/V/0106/001

Concerned member states:
Austria Belgium Croatia Cyprus Czechia Denmark Finland France Greece Hungary Iceland Ireland Italy Netherlands 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

Package Leaflet

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Summary of Product Characteristics

English (PDF)
Published on: 13/02/2025
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Labelling

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