Spasmalgan compositum 500 mg/ml + 4 mg/ml Solution for injection for horses, cattle, pigs and dogs

Authorised

- Hyoscine butylbromide
- Metamizole sodium monohydrate

Product identification

Medicine name:
Spasmalgan compositum 500 mg/ml + 4 mg/ml Solution for injection for horses, cattle, pigs and dogs

Active substance:
Hyoscine butylbromide
Metamizole sodium monohydrate

Target species:
Cattle
Dog
Horse
Pig

Route of administration:
Intravenous use
Intramuscular use

Product details

Active substance and strength:
Hyoscine butylbromide
4.00 milligram(s) / 1.00 millilitre(s)

Metamizole sodium monohydrate
500.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Solution for injection

Withdrawal period by route of administration:
Intravenous use:

- **Cattle**
  - Milk. 96 hour
  - Meat and offal. 12 day
- **Horse**
  - Meat and offal. 12 day
  - Milk. no withdrawal period

Not authorised for use in horses producing milk for human consumption.

Intramuscular use:

- **Pig**
  - Meat and offal. 15 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QA03DB04

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

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Authorisation status:
Valid

Authorised in:
Romania

Available in:
Romania

Package description:
(ID2) 100 millilitre(s): Box (board) with 1 Bottle (clear glass) with 100 millilitre(s), closed with Stopfen (bromobutyl rubber) and Cap`` (aluminium)
(ID1) 10 millilitre(s): Box (board) with 1 Bottle (clear glass) with 10 millilitre(s), closed with Stopfen (bromobutyl rubber) and Cap`` (aluminium)

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:
Veyx Pharma GmbH

Marketing authorisation date:
7/10/2020

Manufacturing sites for batch release:
Veyx Pharma GmbH
Veyx-Pharma B.V.

Responsible authority:
Institute For Control Of Biological Products And Veterinary Medicines

Authorisation number:
250136

Date of authorisation status change:
14/10/2025

Reference member state:
Germany

Procedure number:
DE/V/0323/001

Concerned member states:
Austria Bulgaria Croatia Cyprus Czechia Estonia Greece Hungary Ireland Italy Latvia Lithuania Luxembourg Malta Poland Portugal Romania Slovakia Spain

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

Documents

Combined File of all Documents

English (PDF)
Published on: 4/12/2025
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