# 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
Spasmalgan compositum 500 mg/ml + 4 mg/ml Injekčný roztok pre kone, hovädzí dobytok, ošípané a psy

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**Active substance:**
Hyoscine butylbromide

Metamizole sodium monohydrate

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**Target species:**
Cattle
Dog
Horse
Pig

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**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

**Authorisation status:**
Valid

**Authorised in:**
Slovakia

**Available in:**
Slovakia

**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:**
7/08/2020

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

**Responsible authority:**
Institute For State Control Of Veterinary Biologicals And Medicaments

**Authorisation number:**
96/024/DC/20-S

**Date of authorisation status change:**
10/10/2022

**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

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## Documents

Combined File of all Documents

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