

# 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)

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### **Pharmaceutical form:**

Solution for injection

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### **Withdrawal period by route of administration:**

#### **Intravenous use:**

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#### **Cattle**

- Milk. 96 hour

- Meat and offal. 12 day

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#### **Horse**

- Meat and offal. 12 day

- Milk. no withdrawal period

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

#### **Intramuscular use:**

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#### **Pig**

- Meat and offal. 15 day

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### **Anatomical therapeutic chemical veterinary (ATCvet) codes:**

QA03DB04

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### **Legal status of supply:**

Veterinary medicinal product subject to veterinary prescription

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**Authorisation status:**

Valid

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**Authorised in:**

Slovakia

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**Available in:**

Slovakia

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**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)

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## Additional information

**Entitlement type:**

Marketing Authorisation

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**Legal basis of product authorisation:**

Generic application (Article 13(1) of Directive No 2001/82/EC)

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**Marketing authorisation holder:**

Veyx Pharma GmbH

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**Marketing authorisation date:**

7/08/2020

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**Manufacturing sites for batch release:**

Veyx Pharma GmbH

Veyx-Pharma B.V.

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**Responsible authority:**

Institute For State Control Of Veterinary Biologicals And Medicaments

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**Authorisation number:**

96/024/DC/20-S

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**Date of authorisation status change:**

10/10/2022

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**Reference member state:**

Germany

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**Procedure number:**

DE/V/0323/001

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**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)

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