

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

Authorisation status:

Valid

Authorised in:

Italy

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:

1/01/2022

Manufacturing sites for batch release:

Veyx Pharma GmbH

Veyx-Pharma B.V.

Responsible authority:

Ministry Of Health

Authorisation number:

105360

Date of authorisation status change:

7/06/2022

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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www.adrreports.eu/vet

Documents

Combined File of all Documents

English (PDF)

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