

# Sympagesic 500 mg/ml + 4 mg/ml solution for injection for horses, cattle, pigs and dogs

Authorised

- Metamizole sodium monohydrate
- Hyoscine butylbromide

## Product identification

### Medicine name:

SYMPAGESIC 500 MG/ML + 4 MG/ML SOLUTION FOR INJECTION FOR HORSES, CATTLE, PIGS AND DOGS

Sympagesic 500 mg/ml + 4 mg/ml solution for injection for horses, cattle, pigs and dogs

### Active substance:

Metamizole sodium monohydrate

Hyoscine butylbromide

### Target species:

Cattle

Pig

Dog

Horse

Horse (mare)

### Route of administration:

Intramuscular use

## Product details

### **Active substance and strength:**

Metamizole sodium monohydrate

500.00 milligram(s) / 1.00 millilitre(s)

Hyoscine butylbromide

4.00 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:**

#### **Intramuscular use:**

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##### **Cattle**

- Meat and offal. 28 day
- Milk. no withdrawal period

Not authorised for use in animals producing milk for human consumption. Do not use in pregnant animals which are intended to produce milk for human consumption within 2 months of expected parturition.

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##### **Pig**

- Meat and offal. 15 day

#### **Intravenous use:**

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##### **Cattle**

- Meat and offal. 18 day
- Milk. no withdrawal period

Not authorised for use in animals producing milk for human consumption. Do not use in pregnant animals which are intended to produce milk for human consumption

within 2 months of expected parturition.

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**Pig**

- Meat and offal. 15 day

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**Horse**

- Meat and offal. 15 day

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**Horse (mare)**

- Milk. no withdrawal period

Not authorised for use in animals producing milk for human consumption. Do not use in pregnant animals which are intended to produce milk for human consumption within 2 months of expected parturition.

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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:**

Ireland

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**Package description:**

Cardboard box with vial of 100 ml

Cardboard box with 5 vials of 100 ml

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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:**

Dechra Regulatory B.V.

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**Marketing authorisation date:**

26/06/2019

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**Manufacturing sites for batch release:**

Genera d.d.

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**Responsible authority:**

Health Products Regulatory Authority

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**Authorisation number:**

VPA22622/033/001

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**Date of authorisation status change:**

26/06/2019

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**Reference member state:**

France

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**Procedure number:**

FR/V/0354/001

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**Concerned member states:**

Belgium Bulgaria Croatia Cyprus Czechia Denmark Estonia Finland  
Germany Greece Hungary Iceland Ireland Italy Latvia Lithuania  
Luxembourg Netherlands Norway Poland Portugal Romania Slovakia  
Slovenia Spain Sweden United Kingdom (Northern Ireland)

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To consult adverse reactions on veterinary medicinal products please go to  
[www.adrreports.eu/vet](http://www.adrreports.eu/vet)