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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

Active substance:
Metamizole sodium monohydrate
Hyoscine butylbromide

Target species:
Cattle
Pig
Dog
Horse
Horse (mare)

Route of administration:
Intramuscular use

Intravenous 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)

Pharmaceutical form:
Solution for injection

Withdrawal period by route of administration:
Intramuscular use:

- **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.

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

Intravenous use:

- **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.

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

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QA03DB04

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

Authorisation status:
Valid

Authorised in:
Norway

Available in:
Norway

Package description:
Cardboard box with vial of 100 ml
Cardboard box with 5 vials of 100 ml

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:
Dechra Regulatory B.V.

Marketing authorisation date:
15/09/2019

Manufacturing sites for batch release:
Genera d.d.

Responsible authority:
Norwegian Medical Products Agency

Authorisation number:
18-12326

Date of authorisation status change:
15/09/2019

Reference member state:
France

Procedure number:
FR/V/0354/001

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)

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

Documents

Summary of Product Characteristics

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Combined File of all Documents

Package Leaflet

This document does not exist in this language (English). You can find it in another language below.

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