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Spasmium comp. 500 mg/ml + 4 mg/ml solution for injection

Authorised

- Hyoscine butylbromide
- Metamizole sodium monohydrate

Product identification

Medicine name:
Spasmium comp. 500 mg/ml + 4 mg/ml solution for injection

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**
  - Meat and offal. 12 day
  - Milk. 4 day
- **Horse**
  - Meat and offal. 12 day
  - Milk. no withdrawal period

Not authorised for use in mares 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:
Denmark

Available in:
Denmark

Package description:
(ID1) 100 millilitre(s): unspecified outer container with 1 Vial (Glass) with 100 millilitre(s), closed with Stopper (Bromobutyl Rubber)
(ID2) 500 millilitre(s): unspecified outer container with 5 Vial (Glass) each with 100 millilitre(s), closed with Stopper (Bromobutyl Rubber)

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:
Vetviva Richter GmbH

Marketing authorisation date:
13/07/2015

Manufacturing sites for batch release:
Vetviva Richter GmbH

Responsible authority:
Danish Medicines Agency

Authorisation number:
54527

Date of authorisation status change:
13/07/2015

Reference member state:
Germany

Procedure number:

DE/V/0159/001

Concerned member states:
Austria Bulgaria Croatia Czechia Denmark Estonia Finland Greece Hungary Iceland Ireland Italy Latvia Lithuania 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

2402115-paren-20221212.pdf