PENETHAONE Powder and solvent for suspension for injection for cattle

- Penethamate hydriodide

Authorised

Product identification

Medicine name:
PENETHAONE Powder and solvent for suspension for injection for cattle
Active substance:

- Penethamate hydriodide

Target species:

- Cattle (lactating cow)

Route of administration:

- Intramuscular use

Product details

Active substance and strength:

- Penethamate hydriodide
  236.30
  milligram(s)
  /
  1.00
  millilitre(s)

Pharmaceutical form:

- Powder and solvent for suspension for injection

Withdrawal period by route of administration:

- Intramuscular use
  - Cattle (lactating cow)
    - Meat and offal
      4
      day
    - Milk
      no withdrawal period
      Meat and offal: 4 days; Milk: 2,5 days/60 hours.

Anatomical therapeutic chemical veterinary (ATCvet) codes:

- QJ01CE90

Legal status of supply:

- Veterinary medicinal product subject to veterinary prescription

Authorisation status:

- Valid

Authorised in:

- Norway

Available in:

- Norway

Package description:

- box containing 10 x 10,000,000 IU powder vial and 10 x 36 ml solvent vial
- box containing 5 x 10,000,000 IU powder vial and 5 x 36 ml solvent vial
- box containing 1 x 10,000,000 IU powder vial and 1 x 36 ml solvent vial
- box containing 10 x 5,000,000 IU powder vial and 10 x 18 ml solvent vial
- box containing 5 x 5,000,000 IU powder vial and 5 x 18 ml solvent vial
- box containing 1 x 5,000,000 IU powder vial and 1 x 18 ml solvent vial

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:

- Divasa Farmavic S.A.

Marketing authorisation date:

- 13/05/2015

Manufacturing sites for batch release:

- Divasa Farmavic S.A.

Responsible authority:

- Norwegian Medical Products Agency

Authorisation number:

- 14-10082

Date of authorisation status change:

- 22/04/2020

Reference member state:

- Spain

Procedure number:

- ES/V/0226/001

Concerned member states:

- Austria
- Belgium
- Bulgaria
- Czechia
- Denmark
- France
- Germany
- Greece
- Hungary
- Iceland
- Ireland
- Italy
- Lithuania
- Netherlands
- Norway
- Poland
- Portugal
- Romania
- Slovakia
- Sweden
- United Kingdom (Northern Ireland)

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

Documents

Product information

Summary of Product Characteristics

English (PDF)
Published on: 26/12/2023
Download
Other languages (1)
Norwegian (PDF)
Published on: 15/03/2022
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