PENETHAONE Powder and solvent for suspension for injection for cattle

Authorised

- Penethamate hydriodide

Product identification

Medicine name:
Penethaone 236.3 mg/ml powder and solvent for suspension for injection for cattle
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:
Ireland

Available in:
Ireland

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:
3/09/2015

Manufacturing sites for batch release:
DIVASA-FARMAVIC, S.A.

Responsible authority:
Health Products Regulatory Authority

Authorisation number:
VPA10505/004/001

Date of authorisation status change:
3/09/2015

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

Summary of Product Characteristics