Novomate 277.8 mg/ml Powder and Solvent for Suspension for Injection for Cattle

Authorised

- Penethamate hydriodide

Product identification

Medicine name:
Novomate 277.8 mg/ml Powder and Solvent for Suspension for Injection for Cattle

Active substance:
Penethamate hydriodide

Target species:
Cattle

Route of administration:
Intramuscular use

Product details

Active substance and strength:
Penethamate hydriodide
277.80 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:

Powder and solvent for suspension for injection

Withdrawal period by route of administration:

Intramuscular use:

- **Cattle**
  - Meat and offal. 10 day
  - Milk. 96 hour

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QJ01CE90

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

United Kingdom (Northern Ireland)

Package description:

Powder:Colourless, glass vials (siliconised) (50 ml) (type II) closed with rubber stoppers (bromobutyl) and aluminium caps.Solvent:Colourless, glass vials (50 ml) (type II) closed with rubber stoppers (bromobutyl) and aluminium caps.Pack sizes:Cardboard box with 1 pair of vials (10 g powder and 30 ml solvent) Powder:Colourless, glass vials (siliconised) (30 ml) (type I) closed with rubber stoppers (bromobutyl) and aluminium caps.Solvent:Colourless, glass vials (20 ml) (type I) closed with rubber stoppers (bromobutyl) and aluminium caps.Pack sizes:Cardboard box with 6 pairs of vials (5 g powder and 15 ml solvent) Powder:Colourless, glass vials (siliconised) (30 ml) (type I) closed with rubber stoppers (bromobutyl) and aluminium caps.Solvent:Colourless, glass vials (20 ml) (type I) closed with rubber stoppers (bromobutyl) and aluminium caps.Pack sizes:Cardboard box with 2 pairs of vials (5 g powder and 15 ml solvent) Powder:Colourless, glass vials (siliconised) (30 ml) (type I) closed with rubber stoppers (bromobutyl) and aluminium caps.Solvent:Colourless, glass vials (20 ml) (type I) closed with rubber stoppers (bromobutyl) and aluminium caps.Pack

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Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Hybrid application (Article 13(3) of Directive No 2001/82/EC)

Marketing authorisation holder:
Lohmann Pharma Herstellung GmbH

Marketing authorisation date:
15/12/2015

Manufacturing sites for batch release:
Lohmann Pharma Herstellung GmbH

Responsible authority:
The Veterinary Medicines Directorate

Authorisation number:
Vm 52429/4000

Date of authorisation status change:
19/02/2021

Reference member state:
Ireland

Procedure number:
IE/V/0613/001

Concerned member states:
Austria Belgium Denmark France Netherlands Poland Portugal Spain United Kingdom (Northern Ireland)

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

Documents

Summary of Product Characteristics