# Novomate 277.8 mg/ml powder and solvent for suspension for injection for cattle

Authorised

- Penethamate hydriodide
- Water for injection

#### Product identification

#### Medicine name:

Novomate 277.8 mg/ml Poudre et solvant pour suspension injectable Novomate 277.8 mg/ml Poeder en oplosmiddel voor suspensie voor injectie Novomate 277.8 mg/ml Pulver und Lösungsmittel zur Herstellung einer Injektionssuspension

Novomate 277.8 mg/ml powder and solvent for suspension for injection for cattle

#### **Active substance:**

Penethamate hydriodide Water for injection

# **Target species:**

Cattle

#### Route of administration:

Intramuscular use

# **Product details**

# **Active substance and strength:**

Penethamate hydriodide 277.80 milligram(s) / 1.00 millilitre(s)

Water for injection 1.00 other / 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:

Belgium

#### **Available in:**

Belgium

#### 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 sizes: Cardboard box with 1 pair of vials (5 g powder and 15 ml solvent) 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 6 pairs of vials (10 g powder and 30 ml solvent) 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 2 pairs of vials (10 g powder and 30 ml solvent)

### 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:

This information is not available for this product.

# Manufacturing sites for batch release:

Lohmann Pharma Herstellung GmbH

# **Responsible authority:**

Federal Agency For Medicines And Health Products

#### **Authorisation number:**

This information is not available for this product.

Date of authorisation status change:
24/08/2021

# Reference member state:

Ireland

#### **Procedure number:**

IE/V/0613/001

#### **Concerned member states:**

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

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

Package Leaflet

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

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