Evomate RTU 400 mg/ml

Authorised

- Penethamate hydriodide

Product identification

Medicine name:
Evomate RTU 400 mg/ml
Revozyn RTU, 400mg/ml, Injekční suspenze

Active substance:
Penethamate hydriodide

Target species:
Cattle

Route of administration:
Intramuscular use

Product details

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

Pharmaceutical form:
Suspension for injection

Withdrawal period by route of administration:

Intramuscular use:

- **Cattle**
  - Milk. 4 day
  - Meat and offal. 10 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QJ01CE90

Legal status of supply:
Veterinary medicinal product subject to veterinary prescription

Authorisation status:
Valid

Authorised in:
Czechia

Package description:
Multidose 50 ml uncoloured glass (type II, Ph. Eur.) vial, closed with a fluoropolymer coated rubber type I (Ph. Eur.) stopper, secured with an aluminium cap.

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:
Eurovet Animal Health B.V.

Marketing authorisation date:
12/04/2018

Manufacturing sites for batch release:
Eurovet Animal Health B.V.

Produlab Pharma B.V.

Responsible authority:
Institute For State Control Of Veterinary Biologicals And Medicaments

Authorisation number:
96/022/18-C

Date of authorisation status change:
28/01/2022

Reference member state:
Netherlands

Procedure number:
NL/V/0229/001

Concerned member states:
Austria Belgium Croatia Czechia Denmark France Hungary Ireland Italy Poland Portugal Slovakia Slovenia Spain

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