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Ovarelin 50 ug/ml, solution for injection for cattle

Authorised

- Gonadorelin diacetate tetrahydrate

Product identification

Medicine name:
Ovarelin 50 ug/ml, solution for injection for cattle

Active substance:
Gonadorelin diacetate tetrahydrate

Target species:
Cattle

Route of administration:
Intramuscular use

Product details

Active substance and strength:
Gonadorelin diacetate tetrahydrate
58.13 microgram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Solution for injection

Withdrawal period by route of administration:

Intramuscular use:

- **Cattle**
  - Meat and offal. 0 day
  - Milk. 0 hour

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QH01CA01

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

Authorisation status:
Valid

Authorised in:
Norway

Available in:
Norway

Package description:
Material of the primary container:Colourless glass vial type II (50 ml).Chlorobutyl stopper.Pack size:Box containing 1 glass vial of 50 ml
Material of the primary container:Colourless glass vial type II (20 ml).Chlorobutyl stopper.Pack size:Box containing 1 glass vial of 20 ml
Material of the primary container:Colourless glass vial type II (10 ml).Chlorobutyl stopper.Pack size:Box containing 1 glass vial of 10 ml
Material of the primary container:Colourless glass vial type I (4 ml).Chlorobutyl stopper.Pack size:Box containing 1 glass vial of 4 ml

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Full application (Article 12(3) of Directive No 2001/82/EC)

Marketing authorisation holder:
Ceva Sante Animale

Marketing authorisation date:
26/02/2008

Manufacturing sites for batch release:
Ceva Sante Animale

Responsible authority:
Norwegian Medical Products Agency

Authorisation number:
07-4766

Date of authorisation status change:
15/02/2019

Reference member state:
Ireland

Procedure number:
IE/V/0598/001

Concerned member states:
Austria Belgium Croatia Czechia Denmark Estonia Finland Germany Hungary Latvia Lithuania Luxembourg Netherlands Norway Poland Portugal Slovakia Slovenia 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

English (PDF)
Published on: 25/09/2024
Updated on: 14/03/2026
Download

Package Leaflet

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