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
OVARELIN 50 µg/ml, injekčný roztok pre hovädzí dobytok

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:
Slovakia

Package description:
Material of the primary container:Colourless glass vial type I (4 ml).Chlorobutyl stopper.Pack size:Box containing 1 glass vial of 4 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 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 (50 ml).Chlorobutyl stopper.Pack size:Box containing 1 glass vial of 50 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 Animal Health Slovakia s.r.o.

Marketing authorisation date:
18/10/2012

Manufacturing sites for batch release:
Ceva Sante Animale

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

Authorisation number:
96/061/MR/12-S

Date of authorisation status change:
18/10/2012

Reference member state:
Ireland

Procedure number:
IE/V/0598/001

Concerned member states:
Austria Belgium Bulgaria Croatia Czechia Denmark Estonia Finland France Germany Greece Hungary Italy Latvia Lithuania Luxembourg Netherlands Norway Poland Portugal Romania Slovakia Slovenia Spain Sweden United Kingdom (Northern Ireland)

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

Documents

Combined File of all Documents

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Summary of Product Characteristics
