

# 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

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**Active substance:**

Gonadorelin diacetate tetrahydrate

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**Target species:**

Cattle

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**Route of administration:**

Intramuscular use

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## Product details

**Active substance and strength:**

Gonadorelin diacetate tetrahydrate  
58.13 microgram(s) / 1.00 millilitre(s)

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**Pharmaceutical form:**

Solution for injection

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**Withdrawal period by route of administration:****Intramuscular use:**

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**Cattle**

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

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**Anatomical therapeutic chemical veterinary (ATCvet) codes:**

QH01CA01

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**Legal status of supply:**

Veterinary medicinal product subject to veterinary prescription

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**Authorisation status:**

Valid

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**Authorised in:**

Croatia

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**Available in:**

Croatia

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**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

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## Additional information

**Entitlement type:**

Marketing Authorisation

**Legal basis of product authorisation:**

Full application (Article 12(3) of Directive No 2001/82/EC)

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**Marketing authorisation holder:**

Ceva Sante Animale

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**Marketing authorisation date:**

21/11/2018

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**Manufacturing sites for batch release:**

Ceva Sante Animale

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**Responsible authority:**

Ministry Of Agriculture Veterinary And Food Safety Directorate

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**Authorisation number:**

UP/I-322-05/18-01/562

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**Date of authorisation status change:**

18/07/2024

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**Reference member state:**

Ireland

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**Procedure number:**

IE/V/0598/001

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**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)

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To consult adverse reactions on veterinary medicinal products please go to  
[www.adrreports.eu/vet](http://www.adrreports.eu/vet)

## Documents

Summary of Product Characteristics

English (PDF)

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