ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box of 4 ml vial
Cardboard box of 10 ml vial
Cardboard box of 20 ml vial
Cardboard box of 50 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovarelin 50 µg/ml, solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains 50 µg of gonadorelin (as diacetate tetrahydrate).

3. PACKAGE SIZE

4 ml
10 ml
20 ml
50 ml

4. TARGET SPECIES

Cattle: cows and heifers

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: zero days
Milk: zero hours

8. EXPIRY DATE

Exp. {MM/YYYY}

Once broached use within 28 days, by: ___/___/___

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Keep the container in the outer carton in order to protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only..

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Sante Animale

14. MARKETING AUTHORISATION NUMBER(S)

Vm 14966/3058

15. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

4 ml vial label
10 ml vial label
20 ml vial label
50 ml vial label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovarelin

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

50 µg of gonadorelin per ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp {MM/YYYY}
Once broached use within 28 days, by: ___/___/___

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Ovarelin 50 µg/ml, Solution for Injection for Cattle

2. Composition

1 ml contains:
Active substance: 50 µg of gonadorelin (as diacetate tetrahydrate)
Excipients: 15 mg of benzyl alcohol (E1519).
Clear colourless solution.

3. Target species

Cattle: cows and heifers.

4. Indications for use

Induction and synchronisation of oestrus and ovulation in combination with prostaglandin F_{2a} ($PGF_{2\alpha}$) or analogue with or without progesterone as part of Fixed Time Artificial Insemination (FTAI) protocols.

Treatment of delayed ovulation (repeat breeding).
A repeat breeder cow or heifer is generally defined as an animal that has been inseminated at least 2 or often 3 times without becoming pregnant, despite having regular normal oestrus cycles (every 18 -24 days), normal oestrus behaviour and no clinical abnormalities of the reproductive tract.

5. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special warnings:
The response of dairy cows to synchronisation protocols may be influenced by the physiological state at the time of treatment, which includes age of the cow, body condition and interval from calving.
Responses to treatment are not uniform either across herds or across cows within herds.
Where a period of progesterone treatment is included in the protocol, the percentage of cows displaying oestrus within a given period is usually greater than in untreated cows and the subsequent luteal phase is of normal duration.

Special precautions to be taken by the person administering the veterinary medicinal product to the animals
Gonadorelin is a Gonadotropin Releasing Hormone (GnRH) analogue which stimulates the release of sex hormones. The effects of accidental exposure to GnRH analogues in pregnant women or in women with normal reproductive cycles are unknown. The veterinary medicinal product should not be administered by pregnant women. Women of child-bearing age should administer the veterinary medicinal product with caution.
Care should be taken when handling the veterinary medicinal product to avoid self-injection. In cases of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Care should be taken to avoid skin and eye contact. In cases of skin contact, rinse immediately and thoroughly with water as GnRH analogues can be absorbed through the skin. In cases of accidental contact with the eyes, rinse thoroughly with plenty of water.
People with known hypersensitivity (allergy) to GnRH analogues should avoid contact with the veterinary medicinal product.

Pregnancy:
Laboratory studies in rats and rabbits have not produced any evidence of a teratogenic or embryotoxic effects.
Observations in pregnant cows receiving the veterinary medicinal product in early pregnancy have not shown evidence of negative effects on bovine embryos.
Inadvertent administration to a pregnant animal is unlikely to result in adverse effects.

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose:
After single administration of up to 5 times recommended dose or one to three daily administrations of recommended dose, no measurable signs of either local or general clinical intolerance are observed.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Cattle: cows and heifers.

None.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian.
You can also report any adverse events to the marketing authorisation holder or its local representative, using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

Intramuscular use.
100 µg of gonadorelin (as diacetate) per animal in a single injection:i.e. 2 ml of the veterinary medicinal product per animal.

Judgement on the protocol to be used should be made by the veterinarian responsible for treatment, on the basis of the treatment objectives of the individual herd or cow. The following protocols have been evaluated and could be used:

Induction and synchronisation of oestrus and ovulation in combination with a (PGF2α) or analogue:

- Day 0: First injection of gonadorelin (2 ml of the veterinary medicinal product).
- Day 7: Injection of PGF2α or analogue.
- Day 9: Second injection of gonadorelin (2 ml of the veterinary medicinal product) should be done.

The animal should be inseminated within 16-20 hours after the last injection of the veterinary medicinal product or at observed oestrus if sooner.

Induction and synchronisation of oestrus and ovulation in combination with a (PGF2α) or analogue and a progesterone releasing intravaginal device:
The following FTAI protocols have been commonly reported in the literature:

- Insert progesterone releasing intravaginal device for 7 days.
- Inject gonadorelin (2 ml of the veterinary medicinal product) at the progesterone device insertion.
- Inject a PGF2α or analogue 24 hours prior to device removal.
- FTAI 56 hours after removal of the device, or
- Inject gonadorelin (2 ml of the veterinary medicinal product) 36 hours after progesterone releasing intravaginal device removal and FTAI 16 to 20 hours later.

Treatment of delayed ovulation (repeat-breeding):
GnRH is injected during oestrus.
To improve the pregnancy rates, the following timing of injection and insemination should be followed:
- injection should be performed between 4 and 10 hours after oestrus detection.
- an interval of at least 2 hours between the injection of GnRH and artificial insemination is recommended.
- artificial insemination should be carried out in accordance with the usual field recommendations, i.e., 12 to 24 hours after oestrus detection.

9. Advice on correct administration

10. Withdrawal periods

Meat and offal: zero days. Milk: zero hours.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25°C.
Keep the vial in the outer carton in order to protect from light.

Do not use this veterinary medicinal product after the expiry date stated on the vial after "Exp". The expiry date refers to the last day of that month.
Shelf-life after first opening the container: 28 days.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorization numbers and pack sizes

Vm 14966/3058

Pack sizes:
Box containing 1 glass vial of 4 ml
Box containing 1 glass vial of 10 ml
Box containing 1 glass vial of 20 ml
Box containing 1 glass vial of 50 ml

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. Contact details

Marketing authorisation holder:

Ceva Sante Animale
8 rue de Logrono
33500 Libourne
France

Contact details to report suspected adverse reactions:

Tel: +800 35 22 11 51
E-mail: pharmacovigilance@ceva.com

Local representatives and contact details to report suspected adverse reactions:

Manufacturer responsible for batch release:
Ceva Santé Animale, 10 av. de La Ballastière, 33500 Libourne, France

17. Other information

Gavin Hall
Approved: 17 October 2025