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 for cattle
gonadorelin

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

4 ml
10 ml
20 ml
50 ml

5. TARGET SPECIES

Cattle: cows, heifers

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 15052/4022

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

4 ml
10 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovarelin 50 µg/ml, solution for injection for cattle
gonadorelin
I.M.

4 ml
10 ml

2. NAME OF THE MARKETING AUTHORISATION HOLDER

3. EXPIRY DATE

EXP:

4. BATCH NUMBER

Lot:

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label of 20 ml vial
Label of 50 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovarelin 50 µg/ml, solution for injection for cattle
gonadorelin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

20 ml
50 ml

4. ROUTE(S) OF ADMINISTRATION

I.M.

5. WITHDRAWAL PERIOD(S)

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

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

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

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Ovarelin 50 µg/ml, solution for injection for cattle

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing Authorisation Holder:
Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovarelin 50 µg/ml, solution for injection for cattle
gonadorelin

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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

4. INDICATION(S)

Induction and synchronisation of oestrus and ovulation in combination with prostaglandin $F_{2\alpha}$ ($PGF_{2\alpha}$) 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 œstrus cycles (every 18 -24 days), normal œstrus 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. ADVERSE REACTIONS

None.
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 inform your veterinary surgeon.

7. TARGET SPECIES

Cattle: cows, heifers.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Intramuscular use.
100 µg of gonadorelin (as diacetate) per animal in a single injection.
i.e. 2 ml of the 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 prostaglandin F2α (PGF2α) or analogue:

- Day 0: First injection of gonadorelin (2 ml of the product)
- Day 7: Injection of prostaglandin (PGF2 α) or analogue
- Day 9: Second injection of gonadorelin (2 ml of the product) should be done.

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

Induction and synchronisation of oestrus and ovulation in combination with a prostaglandin F2α (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 product) at the progesterone device insertion.
- Inject a prostaglandin (PGF2 α) or analogue 24 hours prior to device removal
- FTAI 56 hours after removal of the device, or
- Inject gonadorelin (2 ml of the 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 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 WARNING(S)

Special warnings for each target species
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; therefore it is recommended that pregnant women should not administer the product, and that women of child-bearing age should administer the product with caution.

- Care should be taken when handling the 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 eyes, rinse thoroughly with plenty of water.
- People with known hypersensitivity (allergy) to GnRH analogues should avoid contact with the veterinary medicinal product.

Pregnancy and lactation
Laboratory studies in rats and rabbits have not produced any evidence of a teratogenic or embryotoxic effects.

Observations in pregnant cows receiving the 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 (symptoms, emergency procedures, antidotes)
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.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

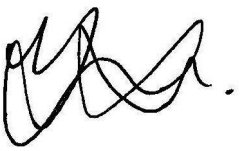
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2022

15. OTHER INFORMATION

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.



Approved: 05 October 2022