

**ANNEX I**

**SUMMARY OF PRODUCT CHARACTERISTICS**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

OVUCRON 0.025 mg/ml solution for injection for cattle and rabbits

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each ml contains:

**Active substance:**

Lecirelin.....0.025 mg  
(equivalent to lecirelin acetate.....0.026 mg)

**Excipients:**

Benzyl alcohol (E1519) .....20 mg

For the full list of excipients, see section 6.1.

**3. PHARMACEUTICAL FORM**

Solution for injection.  
Clear, colourless solution, with no visible particles.

**4. CLINICAL PARTICULARS**

**4.1. Target species**

Cattle (cows) and female rabbits for reproduction.

**4.2. Indications for use, specifying the target species**

Cattle (cows)

Treatment of follicular ovarian cysts.  
Induction of ovulation at the time of insemination in cases of short, silent heat or prolonged heat.

Rabbits

Induction of ovulation.  
Conception rate enhancement.

**4.3. Contraindications**

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

**4.4. Special warnings for each target species**

None.

#### **4.5. Special precautions for use**

##### Special precautions for use in animals

Not applicable.

##### Special precautions to be taken by the person administering the veterinary medicinal product to animals

The effects of accidental exposure 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. Lecirelin has been shown to be foetotoxic in rats.

In case 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 dermal contact as GnRH-analogues may be absorbed through intact skin. In case of dermal contact wash the exposed area immediately with soap and water. People with known hypersensitivity to GnRH analogues should avoid contact with the veterinary medicinal product.

#### **4.6. Adverse reactions (frequency and seriousness)**

None observed.

#### **4.7. Use during pregnancy, lactation or lay**

The use is not recommended during pregnancy.

The product can be used during lactation.

#### **4.8. Interaction with other medicinal products and other forms of interaction**

None known.

#### **4.9. Amounts to be administered and administration route**

Intramuscular use.

The posology varies according to the indications and the animal species, as follows:

##### Cattle (cows)

- Treatment of follicular ovarian cysts: 0.1 mg of lecorelin per animal corresponding to 4 ml of product per animal
- Induction of ovulation at the time of insemination in cases of short, silent heat or prolonged heat: 0.05 mg of lecorelin per animal corresponding to 2 ml of product per animal.

##### Rabbits

- Induction of ovulation: 0.005 mg of lecorelin per animal corresponding to 0.2 ml of product per animal.
- Conception rate enhancement: 0.0075 mg of lecorelin per animal corresponding to 0.3 ml of product per animal.

Treatment may be administered 24 h postpartum.

Mating or insemination must take place immediately after administration.

#### **4.10. Overdose (symptoms, emergency procedures, antidotes), if necessary**

No adverse reactions were recorded in cattle with up to 3 times the recommended dose and in rabbits with up to 2 times the recommended dose.

#### **4.11. Withdrawal periods**

Meat and offal: zero days.

Milk: zero hours.

### **5. PHARMACOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Gonadotropin-releasing hormones

ATCvet code: QH01CA92

#### **5.1. Pharmacodynamic properties**

Lecirelin is a synthetic analogue of gonadotropin releasing hormone (GnRH). It differs by substitution of D-tertiary leucine for glycine at position 6 and replacement of glycine by ethyl amide at position 10. Consequently, it is a nonapeptide.

Due to structural differences between lecirelin and natural GnRH, the lecirelin molecule shows greater persistence at the site of the specific hypophyseal receptors.

The physiological action of the gonadotropins results from stimulating the maturation of the follicle, inducing ovulation and the appearance of corpora lutea in the ovary.

#### **5.2. Pharmacokinetic particulars**

Lecirelin, administered by the intramuscular route, is rapidly absorbed.

Plasma elimination occurs rapidly, whilst the hormonal action persists for several hours, because of greater persistence in binding to the receptor site.

However, pharmacokinetics is species and dose dependent.

GnRH-analogues accumulate primarily in the liver, kidney and hypophysis whereupon they are metabolised enzymatically, producing compounds devoid of pharmacological activity, which are subsequently excreted in the urine.

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1. List of excipients**

Benzyl alcohol (E1519)

Glacial acetic acid (E260)

Disodium phosphate dodecahydrate (E339ii)

Sodium chloride

Water for injections

#### **6.2. Major incompatibilities**

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

#### **6.3. Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

Shelf life after first opening the immediate packaging: 28 days.

#### **6.4. Special precautions for storage**

Store below 25 °C.

Keep the vial in the outer carton in order to protect from light.

#### **6.5. Nature and composition of immediate packaging**

Colourless type I glass vial (2 and 10 ml) or colourless type II glass vial (20 ml), closed with a chlorobutyl rubber stopper type I and sealed with a flip-off aluminium collar, in a cardboard box.

Package sizes:

Box with 15 vials of 2 ml

Box with 1 vial of 10 ml

Box with 1 vial of 20 ml

Not all pack sizes may be marketed.

#### **6.6. Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products**

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

The product should not enter water courses as this may influence reproductive cycle of fish and other aquatic organisms.

### **7. MARKETING AUTHORISATION HOLDER**

FATRO S.p.A. - Via Emilia, 285 - Ozzano dell'Emilia (Bologna), Italy

### **8. MARKETING AUTHORISATION NUMBER(S)**

[To be completed nationally]

### **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: [To be completed nationally]

Date of last renewal: [To be completed nationally]

### **10. DATE OF REVISION OF THE TEXT**

[To be completed nationally]

### **PROHIBITION OF SALE, SUPPLY AND/OR USE**

**ANNEX III**

**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Cardboard box 15 x 2 ml vials**

1 x 10 ml vial

1 x 20 ml vial

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

OVUCRON 0.025 mg/ml solution for injection for cattle and rabbits  
lecirelin

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains:

**Active substance:**

Lecirelin	0.025 mg
(equivalent to lecirelin acetate	0.026 mg)

**3. PHARMACEUTICAL FORM**

Solution for injection

**4. PACKAGE SIZE**

15 x 2 ml

1 x 10 ml

1 x 20 ml

**5. TARGET SPECIES**

Cattle (cows) and female rabbits for reproduction

**6. INDICATION(S)**

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**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Intramuscular use.

posology

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD(S)**

Withdrawal period(s):

Meat and offal: zero days.

Milk: zero hours.



**9. SPECIAL WARNINGS, IF NECESSARY**

Read the package leaflet before use.

**10. EXPIRY DATE**

EXP {month /year}

Once broached, use by:

Shelf life after first opening the immediate packaging: 28 days.

**11. SPECIAL STORAGE CONDITIONS**

Store below 25 °C.

Keep the vial in the outer carton in order to protect from light.

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

Dispose of waste material in accordance with local requirements.

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**

FATRO S.p.A. - Via Emilia, 285- Ozzano dell'Emilia (Bologna), Italy.

**16. MARKETING AUTHORISATION NUMBER(S)**

[To be completed nationally]

**17. MANUFACTURER'S BATCH NUMBER**

Batch {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

Label 2 ml, 10 ml, 20 ml

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

OVUCRON 0.025 mg/ml solution for injection for cattle and rabbits  
lecirelin

**2. QUANTITY OF THE ACTIVE SUBSTANCE**

Each ml contains:

**Active substance:**

Lecirelin	0.025 mg
(equivalent to lecirelin acetate	0.026 mg)

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

2 ml  
10 ml  
20 ml

**4. ROUTE(S) OF ADMINISTRATION**

Intramuscular use

**5. WITHDRAWAL PERIOD(S)**

Withdrawal period(s):

Meat and offal: zero days.

Milk: zero hours.

**6. BATCH NUMBER**

Batch {number}

**7. EXPIRY DATE**

EXP {month /year}

Once broached, use by:

Shelf life after first opening the immediate packaging: 28 days.

**8. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

## **B. PACKAGE LEAFLET**

**PACKAGE LEAFLET:**  
**OVUCRON 0.025 mg/ml solution for injection for cattle and rabbits**

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

Marketing authorisation holder and manufacturer responsible for batch release:

FATRO S.p.A. - Via Emilia, 285 - Ozzano dell'Emilia (Bologna), Italy.

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

OVUCRON 0.025 mg/ml solution for injection for cattle and rabbits  
lecirelin

**3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS**

Each ml contains:

**Active substance:**

Lecirelin.....0.025 mg  
(equivalent to lecirelin acetate.....0.026 mg)

**Excipients:**

Benzyl alcohol (E1519).....20 mg

Clear, colourless solution, with no visible particles.

**4. INDICATIONS**

Cattle (cows)

Treatment of follicular ovarian cysts.

Induction of ovulation at the time of insemination in cases of short, silent heat or prolonged heat.

Rabbits

Induction of ovulation.

Conception rate enhancement.

**5. CONTRAINDICATIONS**

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

**6. ADVERSE REACTIONS**

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.

Alternatively you can report via your national reporting system {national system details}

**7. TARGET SPECIES**

Cattle (cows) and female rabbits for reproduction.

## **8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION**

Administer by the intramuscular route.

The posology varies according to the indications and the animal species, as follows:

### Cattle (cows)

- Treatment of follicular ovarian cysts: 0.1 mg of lecirelin per animal corresponding to 4 ml of product per animal.
- Induction of ovulation at the time of insemination in cases of short, silent heat or prolonged heat: 0.05 mg of lecirelin per animal corresponding to 2 ml of product per animal.

### Rabbits

- Induction of ovulation: 0.005 mg of lecirelin per animal corresponding to 0.2 ml of product per animal.
- Conception rate enhancement: 0.0075 mg of lecirelin per animal corresponding to 0.3 ml of product per animal.

Treatment may be administered 24 h postpartum.

Mating or insemination must take place immediately after administration.

## **9. ADVICE ON CORRECT ADMINISTRATION**

None.

## **10. WITHDRAWAL PERIODS**

Meat and offal: zero days.

Milk: zero hours.

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

Store below 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 which is stated on the vial and carton label after "EXP". The expiry date refers to the last day of that month.

Shelf life after first opening the container: 28 days.

## **12. SPECIAL WARNINGS**

Special warnings for each target species:

None.

Special precautions for use in animals:

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

The effects of accidental exposure 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. Lecirelin has been shown to be foetotoxic in rats.

In case 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 dermal contact as GnRH-analogues may be absorbed through intact skin. In case of dermal contact wash the exposed area immediately with soap and water. People with known hypersensitivity to GnRH analogues should avoid contact with the veterinary medicinal product.

#### Pregnancy and lactation:

The use is not recommended during pregnancy.

The product can be used during lactation.

#### Interaction with other medicinal products and other forms of interaction:

None known.

#### Overdose (symptoms, emergency procedures, antidotes):

No adverse reactions were recorded in cattle with up to 3 times the recommended dose and in rabbits with up to 2 times the recommended dose.

#### 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 MATERIALS, IF ANY**

The product should not enter water courses as this may influence reproductive cycle of fish and other aquatic organisms.

Medicines should not be disposed of via wastewater or household waste.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

### **14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

[To be completed nationally]

### **15. OTHER INFORMATION**

#### **Package sizes:**

Box with 15 vials of 2 ml

Box with 1 vial of 10 ml

Box with 1 vial of 20 ml

Not all pack sizes may be marketed.