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 a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear, colourless solution.

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

None.
Do not use in case 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

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.

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. 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.

Pack 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 product 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 Emilia (Bologna), Italy

8. MARKETING AUTHORISATION NUMBERS

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:

10. DATE OF REVISION OF THE TEXT

{MM/YYYY} or <month YYYY>

PROHIBITION OF SALE, SUPPLY AND/OR USE