SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dalmarelin 25 micrograms/ml solution for injection for cattle and rabbits

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:
Active substance:
Lecirelin acetate equivalent to lecirelin..…….…….... 25 µg

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 (cow) and rabbits.

4.2 Indications for use, specifying the target species

Cattle
- Treatment of follicular ovarian cysts.
- Induction of ovulation in cycling cows in association with artificial insemination to optimise the time of ovulation.

Rabbits
- Induction of ovulation.
- Conception rate enhancement.

4.3 Contraindications

None.

4.4 Special warnings for each target species

The product should be administered to cows with normal ovaries at least 14 days after calving due to the absence of receptivity of the hypophysis before that time. The product should be administered at least 42 days post-partum for the induction of ovulation in association with artificial insemination.

4.5 Special precautions for use

i) Special precautions for use in animals

Animals in poor condition, whether from illness, inadequate nutrition, or other factors, may respond poorly to treatment.

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

Lecirelin has been shown to be foetotoxic in rats. The product should not be administered by pregnant women. Women of child-bearing potential should administer the product with caution. Administration should be performed with care in order to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
GnRH-analogues may be absorbed through intact skin. In case of dermal contact wash the exposed area immediately with soap and water.

4.6 Adverse reactions (frequency and seriousness)

None observed.

4.7 Use during pregnancy, lactation or lay

The use of Dalmarelin is not recommended during pregnancy.
Dalmarelin can be used during lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amount(s) to be administered and administration route

Administer by the intramuscular route.
The closures should not be punctured more than 25 times.
The posology varies according to the indications and the animal species, as follows.

Cattle

- Treatment of follicular ovarian cysts: 4 ml of the product (100 µg of lecirelin).
- Induction of ovulation in cycling cows in association with artificial insemination to optimise the time of ovulation: 2 ml of the product (50 µg of lecirelin). After oestrus detection, the product should be administered at the time of the artificial insemination (AI) or up to 8 hours beforehand. No more than 20 hours should elapse between onset of observable oestrus and AI.

Rabbits

- Induction of ovulation: 0.2 ml.
- Conception rate enhancement: 0.3 ml.

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 period(s)

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Gonadotropin-releasing hormones

ATC Vet Code: QHO1CA92.

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

After intramuscular administration of 50 µg of lecirelin to cows absorption is rapid. The maximum concentration (C_{max}) of 585.5 pg/ml is obtained after 15 - 30 min (T_{max}). Concentrations of lecirelin decreased rapidly with a plasma half-life of approximately 40 min.

Pharmacokinetics is species and dose dependent.

Absorption
Lecirelin, administered by the intramuscular route, is rapidly absorbed in cattle achieving maximal plasma concentrations within 20 minutes.
Plasma elimination occurs rapidly, whilst the hormonal action persists for several hours, because of greater persistence in binding to the receptor site.
In rabbits absorption is also rapid but plasma half-life is slightly longer than in cattle, (approximately 60 min).

Distribution
GnRH-analogues accumulate primarily in the liver, kidney and hypophysis.

Metabolism
GnRH analogues are metabolised enzymatically, producing compounds devoid of pharmacological activity.

Elimination
The inactive compounds are subsequently excreted in the urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E1519)
Glacial acetic acid (E 260)
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

Do not store above 25 °C.

6.5 Nature and composition of immediate packaging

4 or10 ml, type I or 20 ml type II neutral colourless glass vials, closed with a type I rubber stopper and an aluminium overseal, in a cardboard box.
100 ml High Density Polyethylene (HDPE) flexi-pack closed with a type I rubber stopper and an aluminium overseal, in a cardboard box.

Package sizes:
- 1 x 4 ml vial of product per box
- 10 x 4 ml vials of product in a thermoformed PVC blister per box
- 1 x 10 ml vial of product per box
- 5 x 10 ml vials of product in a thermoformed PVC blister per box
- 1 x 20 ml vial of product per box
- 1 x 100 ml flexi-pack per box

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

Medicines should not be disposed of via wastewater. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Fatro S.p.A.
Via Emilia 285
I-40064 Ozzano Dell'Emilia BO
Italy

8. MARKETING AUTHORISATION NUMBER

Vm 11557/5001

9. DATE OF FIRST AUTHORISATION

14 April 2023

10. DATE OF REVISION OF THE TEXT

April 2023

PROHIBITION OF SALE, SUPPLY AND/OR USE

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

Approved 14 April 2023