PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carboard box:
1 x 4 ml vial
10 x 4 ml vials
1 x 10 ml vial
5 x 10 ml vials
1 x 20 ml vial
1 x 100 ml flexi-pack

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

lecirelin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains:
Active substance: lecirelin acetate equivalent to lecirelin 25 µg
Excipients: benzyl alcohol (E1519) 20 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

4 ml
10 x 4 ml
10 ml
5 x 10 ml
20 ml
100 ml

5. TARGET SPECIES

Cattle (cow) and rabbits.

6. INDICATION(S)

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7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular administration.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Pregnant women should not administer this product. See package leaflet for full user warnings.

10. EXPIRY DATE

EXP …….
Shelf life after first opening the container: 28 days
Once opened, use by _____

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.
Keep the container in the outer carton

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

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

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.

POM-V

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.

Distributed by:
DUGV (UK) Ltd.
Union House
111 New Union Street
Coventry, CV1 2NT

16. MARKETING AUTHORISATION NUMBER(S)

Vm 11557/5001

17. MANUFACTURER'S BATCH NUMBER

Batch ……

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label
100 ml flexi-pack

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

lecirelin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains:
Active substance: lecirelin acetate equivalent to lecirelin 25 µg
Excipients: benzyl alcohol (E1519) 20 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle (cow) and rabbits.

6. INDICATION(S)

---

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular administration.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP …….
Shelf-life after first opening the container: 28 days
Once opened, use by _____

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.

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

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

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.

POM-V

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.

Distributed by:
DUGV (UK) Ltd.
Union House
111 New Union Street
Coventry, CV1 2NT

16. MARKETING AUTHORISATION NUMBER(S)

Vm 11557/5001

17. MANUFACTURER'S BATCH NUMBER

Batch ……

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label
4 ml vial
10 ml vial
20 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

lecirelin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Lecirelin 25 µg/ml

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

4 ml
10 ml
20 ml

4. ROUTE(S) OF ADMINISTRATION

For i.m. administration.

5. WITHDRAWAL PERIOD

Meat/offal/milk: Zero days.

6. BATCH NUMBER

Batch……

7. EXPIRY DATE

EXP …….
Shelf-life after first opening the container: 28 days
Once opened, use by _____

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET FOR:

Dalmarelin 25 micrograms/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

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

1 ml contains:
Active substance: lecirelin acetate equivalent to lecirelin 25 µg
Excipients: benzyl alcohol (E1519) 20 mg

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

None observed.
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 (cow) and rabbits.

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

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.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD(S)

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 container in the outer carton.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton after “EXP”. The expiry date refers to the last day of that month.

Shelf-life after first opening the container: 28 days.

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

12. SPECIAL WARNING(S)

For Animal Treatment Only

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.

Special precautions for use in animals
Animals in poor condition, whether from illness, inadequate nutrition, or other factors, may respond poorly to treatment.

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.

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

Interactions with other medicinal products and other forms of interaction
None known.

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.

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

Medicines should not be disposed of via wastewater. 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

……..

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

15. OTHER INFORMATION

To be supplied only on veterinary prescription.

POM-V

Vm 11557/5001

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.

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.

Package sizes:

- 1 x 4 ml vial
- 10 x 4 ml vials
- 1 x 10 ml vial
- 5 x 10 ml vials
- 1 x 20 ml vial
- 1 x 100 ml flexi-pack container

Not all pack sizes may be marketed.

Distributed by:
DUGV (UK) Ltd.
Union House
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Coventry, CV1 2NT

Approved 14 April 2023