ANNEX III

LABELLING AND PACKAGE LEAFLET

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box with 1 vial f 20 ml
Cardboard box with 5 vial of 20 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Geslin 0.0040 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Buserelin .....0.0040 mg
(equivalent to 0.0042 mg buserelin acetate)

3. PACKAGE SIZE

20 ml
5x20 ml

4. TARGET SPECIES

Cattle (cows), horse (mares), pig (sows and gilts) and rabbit (female rabbit for reproduction).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular, subcutaneous, or intravenous use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal (cow, mare, sow for reproduction and rabbit female for reproduction): Zero days.
Milk (cow and mare): Zero days.

8. EXPIRY DATE

Exp.: {mm/yyyy}
Once opened use by…

9. SPECIAL STORAGE PRECAUTIONS

Store below 25ºC.
Keep the vial in the outer carton in order to protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

MEVET S.A.U.

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Geslin

2. STATEMENT OF ACTIVE SUBSTANCES

Buserelin (acetate) 0.0040 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp.: {mm/yyyy}
Once opened use by…

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Geslin 0.0040 mg/ml solution for injection for cattle, horse, pig, and rabbit

2. Composition

Each ml contains:
Active substance:
Buserelin ..... 0.0040 mg
(equivalent to 0.0042 mg buserelin acetate)
Excipient:
Benzyl alcohol (E 1519)..... 20 mg

Clear, colourless solution

3. Target species

Cattle (cow), horse (mare), pig (sow for reproduction) and rabbit (female for reproduction).

4. Indications for use

Cattle (cow):
- Treatment of follicular cysts.
- Anoestrus due to acyclia (not due to the presence of corpus luteum).
- Improvement of conception rate in females with a history of delayed ovulation.
- Follicular atresia.
- Improving the conception rate in artificial insemination or mating.

Horse (mare):
- Treatment of follicular cysts.
- Anovulation associated with prolonged oestrus despite the presence of a mature follicle
- Ovulation induction.

Pig (sow for reproduction):
- For ovulation induction.

Rabbit (female for reproduction):
- Ovulation induction postpartum.
- Improving the conception rate in insemination or mating.

5. Contraindications

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

6. Special warnings

Do not disinfect syringes or needles with alcohol or phenols.

Special warnings:

Treatment with a GnRH analogue is solely symptomatic and does not eliminate the underlying causes of the fertility disorder.

Cattle

Administer the veterinary medicinal product at least 14 days post-partum due to the absence of pituitary receptivity before this time.

In the treatment of ovarian cysts, a clinical veterinarian should diagnose and confirm the condition of the follicular cyst.

Special precautions for safe use in the target species:

Use aseptic procedures to inject the product. Infection may occur if anaerobic bacteria penetrate the tissue at the injection site, in particular following intramuscular injection.

Administration is recommended when the ovarian follicle is sufficiently developed or mature and according to established reproductive protocols.

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

Because of the potential for effects on reproductive function, women of child-bearing age should handle this veterinary medicinal product with caution. Pregnant women should not administer the product.

When administering the product, care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or label to the doctor.

Avoid eye and skin contact with the veterinary medicinal product. In case of accidental eye contact, rinse thoroughly with water. Should skin contact with the product occur, wash the exposed area immediately with soap and water.

Benzyl alcohol may cause hypersensitivity reactions (allergy). People with known hypersensitivity to benzyl alcohol should administer the veterinary medicinal product with caution.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy or lactation.

The use of this medicinal product during pregnancy or lactation is not recommended.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose:

None described.

Special restrictions for use and special conditions for use:

To be completed in accordance with national requirements after conclusion of the MRP.

Major incompatibilities:

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

7. Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: *To be completed in accordance with national requirements after conclusion of the MRP/DCP/SRP*.

8. Dosage for each species, routes and method of administration

Intramuscular, subcutaneous, or intravenous use.

Cattle (cows):

- Treatment of follicular cysts: 0.020 mg of buserelin/animal (equivalent to 5 ml of veterinary medicinal product/animal) in a single dose. If no corpora lutea are detected 10-14 days after application, the treatment must be repeated.

- Acyclia: 0.020 mg of buserelin/animal (equivalent to 5 ml of veterinary medicinal product/animal) in a single dose. Oestrus will occur 8-22 days later. Nevertheless, if oestrus has not occurred after 10-12 days, a control palpation should be performed. Alternatively, progesterone in milk may be determined. The treatment should be repeated at this first point if the ovaries have not started to function. If, however, a corpus luteum is palpated, then luteolytic prostaglandin should be administered to induce oestrus or wait for natural oestrus to occur, which will present 10-12 days afterwards.

- Improvement of fertility in cows with delayed ovulation: 0.010 mg of buserelin/animal (equivalent to 2.5 ml of veterinary medicinal product/animal) in a single dose.

- Follicular atresia: 0.010 mg of buserelin/animal (equivalent to 2.5 ml of veterinary medicinal product/animal) in a single dose.

- Improving the conception rate in artificial insemination or mating: 0.010 mg of buserelin/animal (equivalent to 2.5 ml of veterinary medicinal product/animal) in a single dose 8 hours before or just before insemination or mating. Alternatively, the same dose of 0.010 mg of buserelin/animal (equivalent to 2.5 ml of veterinary medicinal product/animal) may be given 11-12 days after insemination to prevent luteolysis and consequent embryo mortality.

Horse (mare):

- Treatment of follicular cysts: 0.040 mg of buserelin/animal (equivalent to 10 ml of veterinary medicinal product/animal) in a single dose. If no corpora lutea are detected 10-14 days after application, the treatment must be repeated.

- Anovulation with prolonged oestrus and well-developed follicle: 0.040 mg of buserelin/animal (equivalent to 10 ml of veterinary medicinal product/animal) in a single dose.

- Improving the conception rate: 0.040 mg of buserelin/animal (equivalent to 10 ml of veterinary medicinal product/animal) in a single dose 6 hours before or just before mating.

Pig (sow for reproduction):

- Ovulation induction: 0.010 mg of buserelin/animal (equivalent to 2.5 ml of veterinary medicinal product/animal) in a single dose.

Rabbit (female for reproduction):

- Post-partum ovulation induction: 0.0008 mg of buserelin/animal (equivalent to 0.2 ml of veterinary medicinal product/animal) in a single dose 24 hours post-partum. Insemination should be performed immediately after administration.

To increase the conception rate, the buserelin should be applied during artificial insemination or mating.

9. Advice on correct administration

Do not puncture the stopper more than 20 times.
To ensure a correct dosage, body weight should be determined as accurately as possible.
The use of suitably calibrated measuring equipment is recommended.

10. Withdrawal periods

Meat and offal (cow, mare, sow for reproduction and rabbit female for reproduction): Zero days.
Milk (cow and mare): Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store below 25ºC.
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 label or on the box after Exp. The expiry date refers to the last day of that month.

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

12. Special precautions for disposal

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

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription

14. Marketing authorisation numbers and pack sizes

Pack sizes:
Cardboard box with 1 vial of 20 ml.
Cardboard box with 5 vials of 20 ml.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

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