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ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Buserelin ..... 0.0040 mg
(equivalent to 0.0042 mg buserelin acetate)

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Benzyl alcohol (E 1519)	20 mg
Sodium chloride	
Sodium dihydrogen phosphate monohydrate	
Sodium hydroxide (for pH adjustment)	
Hydrochloric acid, concentrated (for pH adjustment)	
Water for injections	

Clear, colourless solution

3. CLINICAL INFORMATION

3.1 Target species

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

3.2 Indications for use for each target species

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):

- Ovulation induction.

Rabbit (female for reproduction):

- Ovulation induction postpartum.
- Improving the conception rate in insemination or mating.

3.3 Contraindications

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

3.4 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.

3.5 Special precautions for use

Do not disinfect syringes or needles with alcohol or phenols.

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None known.
Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

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

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Intramuscular, subcutaneous, or intravenous use.

Cattle (cow):

- *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.

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

None described.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

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

3.12 Withdrawal periods

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QH01CA90

4.2 Pharmacodynamics

Buserelin is a synthetic peptide hormone with a function analogous to the natural gonadotropin-releasing hormone (GnRH).

It induces the release of the luteinizing hormone (LH) and the follicle-stimulating hormone (FSH) from the anterior pituitary gland in the blood, approximately 1 to 2 hours after administration. The LH peak stimulates the ovulation of ripe follicles at defined points in time.

In cattle, for instance, the majority of the animals are expected to ovulate approximately 24 to 48 hours after the buserelin injection.

In pigs, the majority of the animals are expected to start ovulating approximately 38 to 44 hours after the buserelin injection.

Higher-than-recommended dosages do not have an additional stimulating effect on LH and FSH secretion and do not have an increased positive effect on conception rates.

4.3 Pharmacokinetics

Buserelin is quickly absorbed from the injection site and its metabolism is complete in 24 hours.

In in vivo pharmacokinetic studies (rats, guinea pigs, rabbits and cows), i.v.-administered buserelin was eliminated rapidly from the blood stream with a half-life of 5 minutes in rats and 12 minutes in guinea pigs. The molecule accumulates in the pituitary gland, liver and kidney, where it is enzymatically broken down into shorter peptide fragments with inappreciable biological activity. It is excreted mainly via the kidneys.

In studies performed in pigs that were given an i.m. dose of 10 µg of buserelin, the LH levels obtained were evaluated, and it was calculated that the mean maximum induced effect (Cmax: 8.95 ng/ml) occurred at a mean time of 1.5 hours.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening of the immediate packaging: 28 days.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Type I colourless glass vial closed with bromobutyl rubber stopper and sealed with aluminium cap.

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.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

MEVET S.A.U.

7. MARKETING AUTHORISATION NUMBER

8. DATE OF FIRST AUTHORISATION

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription

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