ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FERTIGEST 0.004 mg/ml Solution for Injection
Buserelin acetate

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:
Buserelin.....0.004 mg
(corresponding to 0.0042 mg buserelin acetate)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

20 ml
5 x 20 ml

5. TARGET SPECIES

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

6. INDICATIONS

*[Indication to be included **only** for medicinal products **not** subject to medical prescription.]*

7. METHOD AND ROUTES OF ADMINISTRATION

Intramuscular or subcutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal periods:

Cattle, horse, pig and rabbit
Meat and offal: Zero days.

Cattle and horse
Milk: Zero hours.

9. SPECIAL WARNINGS, IF NECESSARY

Buserelin has been shown to be foetotoxic in laboratory animals; therefore, pregnant women should not handle the veterinary medicinal product.

10. EXPIRY DATE

EXP
Shelf life after first opening the immediate packaging: 28 days
Once broached, use by…

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.
Keep the vial in the outer carton in order to protect from light.

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

Disposal: read package leaflet.

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.

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

Vetpharma Animal Health, S.L
Gran Via Carles III, 98, 7a
08028 Barcelona
Spain

Local representative:

16. MARKETING AUTHORISATION NUMBER(S)

Vm 32509/4023

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FERTIGEST 0.004 mg/ml Solution for Injection
Buserelin acetate

2. QUANTITY OF THE ACTIVE SUBSTANCE

Buserelin.....0.004 mg
(corresponding to 0.0042 mg buserelin acetate)

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

20 ml

4. ROUTES OF ADMINISTRATION

Intramuscular or subcutaneous use.
Read the package leaflet before use.

5. WITHDRAWAL PERIOD

Withdrawal periods:

Cattle, horse, pig and rabbit
Meat and offal: Zero days.

Cattle and horse
Milk: Zero hours.

6. BATCH NUMBER

Batch

7. EXPIRY DATE

EXP {month/year}
Once broached, use by…

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

FERTIGEST 0.004 mg/ml Solution for Injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Vetpharma Animal Health, S.L
Gran Via Carles III, 98, 7a
08028 Barcelona
Spain

Manufacturer responsible for batch release:
MEVET S.A.U.
Polígono Industrial El Segre, p. 409-410,
25191 Lleida
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

FERTIGEST 0.004 mg/ml Solution for Injection
Buserelin acetate

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each ml contains:

Active substance:
Buserelin.....0.004 mg
(corresponding to 0.0042 mg buserelin acetate)

Excipients:
Benzyl Alcohol (E1519) .....20 mg

Clear, colourless solution

4. INDICATIONS

Cattle:
- Treatment of follicular cysts.
- Improvement of conception rate in artificial insemination procedures.
- Synchronisation of oestrus and ovulation in cyclical cattle, for artificial insemination at a fixed time together with prostaglandin F2α administration.

Horse:
- Treatment of follicular cysts.
- Ovulation induction to synchroniseovulation more closely with mating.

Pig:
- Ovulation induction after oestrus synchronisation by weaning (sows) or by administering a progestagen (gilts) that can be used as part of a single fixed-time artificial insemination programme.

Rabbit:
- Improving the conception rate.
- Ovulation induction postpartum.

5. CONTRAINDICATIONS

Do not use in animals with known hypersensitivity to the active ingredient or to the excipients.

6. ADVERSE REACTIONS

None known

If you notice any side effects or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

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

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Intramuscular or subcutaneous use.

Cattle:
- Follicular cysts: 5 ml of veterinary medicinal product (0.021 mg of buserelin acetate) per animal.
- Improved conception rate: 2.5 ml of veterinary medicinal product (0.0105 mg of buserelin acetate) per animal, administered between the start of oestrus up to and including the time of artificial insemination.
- Synchronisation of oestrus and ovulation in cyclical cattle: 2.5 ml of veterinary medicinal product (0.0105 mg of buserelin acetate) per animal. The following protocol can be applied: 0.0105 mg of buserelin acetate on Day 0, followed by a prostaglandin injection 7 days later and a second injection of 0.0105 mg of buserelin acetate 48 hours after the administration of prostaglandin. Fixed-time artificial insemination can take place 12 to 24 hours after the second buserelin acetate injection.

Horse: 10 ml of veterinary medicinal product (0.042 mg of buserelin acetate) per animal.
The product should be administered on the first day on which the follicle has reached its maximum size. The product is best given approximately 6 hours prior to service. The mare should be served again the next morning if she is still in oestrus. If ovulation has not occurred within 24 hours after treatment, then the injection should be repeated.

Rabbit: 0.2 ml of veterinary medicinal product (0.00084 mg of buserelin acetate) per animal.
- Ovulation induction postpartum: 0.2 ml after parturition, insemination should be carried out directly after administration
- Improving the conception rate: inject 0.2 ml at the time of insemination or mating.

Pig: 2.5 ml of veterinary medicinal product (0.011 mg of buserelin acetate) per animal.

The artificial insemination schedule for pigs is the following:

Gilt:
- Administer 2.5 ml of the veterinary medicinal product 115 to 120 hours after the end of the synchronisation treatment with a progestagen.
- Carry out single artificial insemination 30 to 33 hours after administering the veterinary medicinal product.

Sow:
- Administer 2.5 ml of the veterinary medicinal product 83 to 89 hours after weaning.
- A single artificial insemination should be carried out 30 to 33 hours after administering the veterinary medicinal product.

In individual cases, the oestrus may still not be visible 30 to 33 hours after treatment with the veterinary medicinal product. In these cases, insemination may be carried out at a later time, when signs of heat are present.

9. ADVICE ON CORRECT ADMINISTRATION

In cattle, horses and rabbits, the preferred route of administration is intramuscular injection, but it may also be injected subcutaneously. In pigs, the preferred route of administration is intramuscular.

The rubber stopper may be safely puncture up to 20 times.

10. WITHDRAWAL PERIODS

Cattle, horse, pig and rabbit
Meat and offal: Zero days.

Cattle and horse
Milk: Zero hours.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25 °C.
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 vial and carton after “EXP”. The expiry date refers to the last day of that month.

Shelf life after first opening the container: 28 days

12. SPECIAL WARNINGS

Special warnings for each target species:

Cattle:
Cattle with a short interval between calving and insemination (< 60 days), a low Body Condition Score or high parity may display a lower pregnancy rate after a standard synchronisation protocol (see section: Dosage for each species, routes and method of administration). There is no guarantee that all cows that were synchronised according to the protocol will be in oestrus at the time of artificial insemination. The chances of conception may be higher if the cow is in oestrus at the time of insemination.
To maximise conception rates of cows to be treated, the ovarian status should be determined and regular cyclic ovarian activity confirmed. Optimal results will be achieved in healthy normally-cycling cows.

Pig:
The buserelin administration is purely zootechnical in nature. Buserelin is administered after oestrus synchronisation. Buserelin is administered to gilts after treatment with a progestagen. The consequence of the progestagen treatment is that, if it is terminated simultaneously, the fertility cycles of treated animals are synchronised. Oestrus synchronisation is achieved naturally in sows by weaning. Insemination may be performed 30 to 33 hours after injection. It is recommended that a boar is present at the time of artificial insemination and the animal should be checked for signs of heat prior to insemination.
A negative energy balance during lactation could in some cases be associated with the mobilisation of bodily reserves, with a significant decrease of the thickness of the back fat (more than approximately 30%). These animals could suffer from delayed oestrus and ovulation and should be cared for and bred individually.

Special precautions for use in animals:
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.

Pigs:
If the recommended time schedule is not carefully followed, fertility may be impaired.
Progestins and buserelin can only be used in healthy animals.

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

Buserelin has been shown to be foetotoxic in laboratory animals; therefore, pregnant women should not handle the veterinary medicinal product. Women of child-bearing age should administer the product with caution.
Avoid eye and skin contact with the product.
In case of accidental contact, rinse thoroughly with water. Should skin contact with the product occur, wash the exposed area immediately with soap and water, as GnRH analogues may be absorbed through the skin. Wash hands after use.
When administering the product, care should be taken to avoid accidental self-injection by ensuring that animals are suitably restrained and the application needle is shielded until the moment of injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Do not eat, drink or smoke while handling the product.

Pregnancy and lactation

Do not use during pregnancy.
The veterinary medicinal product can be safely used during lactation.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose (symptoms, emergency procedures, antidotes):

Buserelin only has minor toxicity; even when the recommended dose is exceeded, intoxication is not likely to occur.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

15. OTHER INFORMATION

Carton box with 1 vial of 20ml.
Carton box with 5 vial of 20ml.
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Gavin Hall
Approved: 20 November 2024