ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard carton containing one 10ml vial
Cardboard carton containing one 20 ml vial
Cardboard carton containing 5 vials of 10 ml.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Veterelin 0.004 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance:
Buserelin .....0.004 mg/ml
(equivalent to 0.0042 mg of Buserelin acetate)

3. PACKAGE SIZE

10 ml
20 ml
5x10 ml

4. TARGET SPECIES

Cattle (cows), horses (mares), pigs (sows and gilts) and rabbits (female rabbits for reproduction).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cattle, horses and rabbits: Preferably intramuscular use, but intravenous use or subcutaneous use may also be used.
Pigs: Preferably intramuscular use, but intravenous use may also be used.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: zero days
Milk: zero hours

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 8 hours.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.
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

Laboratorios Calier, S.A.

14. MARKETING AUTHORISATION NUMBERS

Vm 20634/3001

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGE UNITS

Adhesive label for 10 ml or 20 ml vial.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Veterelin

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Buserelin .....0.004 mg/ml
(equivalent to 0.0042 mg of Buserelin acetate)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 8 hours.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Veterelin 0.004 mg/ml solution for injection for cattle, pigs, horses and rabbits

2. Composition

Each ml contains:

Active substance:
Buserelin.....0.004 mg
(equivalent to 0.0042 mg of 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)	10 mg
Sodium chloride	
Sodium dihydrogen phosphate monohydrate	
Sodium hydroxide	
Water for injection	

Clear and colourless solution.

3. Target species

Cattle (cows), horses (mares), pigs (sows and gilts) and rabbits (female rabbits for reproduction).

4. Indications for use

For cows:
- Ovulation induction or delayed ovulation
- Treatment of anoestrus
- Treatment of follicular cysts with or without symptoms of nymphomania
- Improvement of conception rate in artificial insemination procedures, also after synchronisation of oestrus with a PGF2α analogue. Results may however vary depending on breeding conditions.

For mares:
- Ovulation induction and thereby to synchronise ovulation more closely with mating in mares.
- Treatment of follicular cysts – with or without symptoms of nymphomania

For female rabbits for reproduction:
Improvement of conception rate and ovulation induction at post-partum insemination.

For sows (sexually mature gilts):
Ovulation induction after oestrus synchronisation with an analogue of progestagen (altrenogest) in order to perform a single artificial insemination.

5. Contraindications

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

6. Special warnings

Special warnings:

Treatment with a GnRH (gonadotrophin releasing hormone) analogue is only symptomatic; the causes underlying a fertility disorder are not eliminated by this treatment.

Special precautions for safe use in the target species:

Sows (sexually mature gilts): Use of the veterinary medicinal product contrary to the recommended protocols may result in the formation of follicular cysts which may detrimentally affect fertility and prolificacy. An aseptic technique is recommended.

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

Avoid eye and skin contact with the solution for injection. In case of accidental eye contact, rinse thoroughly with water. Should skin contact with the veterinary medicinal product occur, wash the exposed area immediately with soap and water, as GnRH analogues may be absorbed through the skin.

People with known hypersensitivity to buserelin should avoid contact with the veterinary medicinal product.

The veterinary medicinal product should not be administered by pregnant women, as buserelin has been shown to be foetotoxic in laboratory animals.

Women of child-bearing age should administer the veterinary medicinal product with caution.

When administering the veterinary medicinal 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. Wash hands after use.

Pregnancy and lactation:

The use is not recommended during pregnancy or lactation.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose:

In the case of repeated administrations of a dose corresponding to 3.5 ml of veterinary medicinal product, reduced food consumption may be observed in sows (sexually mature gilts) after the 2nd injection. This effect is transient and no specific treatment is required.

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 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 or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

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

In cattle, horses and rabbits, the preferred route of administration is intramuscular injection (i.m.), but it may also be injected intravenously (i.v.) or subcutaneously (s.c.).

In pigs, the preferred route of administration is intramuscularly (i.m.), but it may also be injected intravenously (i.v.).

Species	Indication	µg Buserelin per animal	ml Veterelin 4µg/ml per animal
Cows	Treatment of anoestrus	20	5
	Ovulation induction	20	5
	Delayed ovulation	10	2.5
	Improvement of conception rate in artificial insemination procedures, also after synchronisation of oestrus with a PGF2α analogue. Results may however vary depending on breeding conditions. For oestrus synchronisation in cows according to a 10 day fixed time insemination regime, the buserelin should be administered at day 0 followed by PGF2alpha treatment at day 7, and a second buserelin treatment at day 9 according to the mentioned posology	10	2.5
	Follicular cysts with or without symptoms of nymphomania	20	5
Mares	Treatment of follicular cysts -with or without symptoms of nymphomania.	40	10
	Ovulation induction and thereby to synchronize ovulation more closely with mating in mares.	40	10
Sows (sexually mature gilts)	Ovulation induction after oestrus synchronization with an analogue of progestagen (altrenogest) in order to perform a single artificial insemination. Administration should be done 115-120 hours after the end of synchronization with a progestagen. A single artificial insemination should be performed 30-33 hours after VETERELIN administration	10	2.5
Female rabbits for reproduction	Improvement of conception rate	0.8	0.2
	Ovulation induction at post-partum insemination	0.8	0.2

The veterinary medicinal product should be administered once.

9. Advice on correct administration

The vial can only be broached a maximum of 20 times.

10. Withdrawal periods

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 ºC.
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 after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 8 hours

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

Vm 20634/3001

Pack sizes:
1 x 10 ml vial
1 x 20 ml vial
5 x 10 ml vial

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>:

Manufacturer responsible for batch release:
LABORATORIOS CALIER, S.A.
C/Barcelonès, 26
Polígono Industrial El Ramassar
08520 Les Franqueses del Vallès
Barcelona
Spain

Local representative and contact details to report suspected adverse reactions:

17. Other information

Approved 28 July 2023