

[Version 9,03/2022]corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Buserelin 0.004 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	
Water for injection	

Clear and colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

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

3.2 Indications for use for each target species

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 PGF₂ α 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.

3.3 Contraindications

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

3.4 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

In 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 or benzyl alcohol 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.

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 its local representative or the national competent authority via the national reporting system. See package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

The use is not recommended during pregnancy or lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

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, 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.

The vial can only be broached a maximum of 20 times. An automatic syringe device, or a suitable withdrawal needle, must be used to avoid excessive perforation of the closure.

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

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.

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

3.12 Withdrawal periods

Meat and offal: zero days

Milk: zero hours

4. PHARMACOLOGICAL INFORMATION

4.1 ATCVet Code: QH01CA90

4.2 Pharmacodynamics

Buserelin is a peptide hormone which is chemically analogous to the releasing hormone (RH) of the luteinising hormone (LH) and follicle stimulating hormone (FSH) thus a GnRH analogue.

The mode of action of the veterinary medicinal product corresponds to the physiologic-endocrinological action of the naturally occurring GnRH.

GnRH leaves the hypothalamus via the hypophyseal portal vessels and enters the anterior lobe of the hypophysis. Here it induces the secretion of the two gonadotrophins: FSH and LH into the peripheral blood stream. These can act physiologically to cause maturation of ovarian follicles, ovulation and lutenization in the ovary.

4.3 Pharmacokinetics

After intravenous administration, buserelin is degraded rapidly: its half-life is 3 to 4.5 minutes in rats and 12 minutes in guinea pigs. Buserelin is accumulated in the pituitary gland, liver and kidneys where the substance is degraded by enzymes into small peptide fragments with negligible biologic activity. The main excretion route is in the urine.

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 the immediate packaging: 28 days

5.3 Special precautions for storage

Do not store above 25°C.

Keep the vial in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

Colourless glass vials of 10 or 20 or 100 ml, with bromobutyl rubber closure and aluminium capsules with Flip-off opening ring in PP of blue colour.

Box containing:

1 x 10 ml vial

1 x 20 ml vial

5 x 10 ml vial

1 x 100 ml vial

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

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>).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box containing one 10 ml vial
Cardboard box containing one 20 ml vial
Cardboard box containing 5 vials of 10 ml.
Cardboard box containing one 100 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Veterelin 0.004 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance:

Buserelin0.004 mg/ml
(equivalent to 0.0042 mg of Buserelin acetate)

3. PACKAGE SIZE

10 ml
20 ml
5x10 ml
100 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 28 days.

Once broached use by ...

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”
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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

14. MARKETING AUTHORISATION NUMBERS
--

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
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Veterelin

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Buserelin0.004 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 28 days.
Once broached use by ...

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Adhesive label for 100 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Veterelin 0.004 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Buserelin0.004 mg/ml
(equivalent to 0.0042 mg of Buserelin acetate)

3. TARGET SPECIES

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

4. 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.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period

Meat and offal: zero days

Milk: zero hours

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

Once broached use by ...

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

Keep the vial in the outer carton in order to protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER
--

9. BATCH NUMBER

Lot {number}

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)	20 mg

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 PGF2 α 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 or benzyl alcohol 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. An automatic syringe device, or a suitable withdrawal needle, must be used to avoid excessive perforation of the closure.

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 °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 label 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:

1 x 10 ml vial
1 x 20 ml vial
5 x 10 ml vial
1 x 100 ml vial

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

MM/YYYY

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 Ramassà
Les Franqueses del Vallès. Barcelona
08520 Spain

Local representative and contact details to report suspected adverse reactions:

17. Other information

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