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:
Benzyl alcohol (E 1519).....10 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection.

Clear and colourless solution.

4. CLINICAL PARTICULARS

4.1 Target species

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

4.2 Indications for use, specifying the 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 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.

4.3 Contraindications

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

4.4 Special warnings for each target species

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

4.5 Special precautions for use

i. Special precautions for use in animals

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.

ii. 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 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 the product, as buserelin has been shown to be foetotoxic in laboratory animals.
Women of child-bearing age should administer the 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 aplicable

Other precautions:

Not aplicable

4.6 Adverse reactions (frequency and seriousness)

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 also the last section of the package leaflet for respective contact details.

4.7 Use during pregnancy and lactation or lay

Pregnancy and lactation:

The use is not recommended during pregnancy or lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Meat and offal: zero days
Milk: zero hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Gonadotropin-releasing hormones
ATCvet Code: QH01CA90

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E 1519)
Sodium chloride
Sodium dihydrogen phosphate monohydrate
Sodium hydroxide
Water for injections

6.2 Major Incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening the immediate packaging: 8 hours

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Colourless glass vials of 10 (or 20) 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

Not all pack sizes may be marketed.

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

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

7. MARKETING AUTHORISATION HOLDER

Laboratorios Calier, S.A.
C/Barcelonès 26 (Pla del Ramassà)
08520 Les Franqueses del Vallès
Spain

8. MARKETING AUTHORISATION NUMBER

Vm 20634/5003

9. DATE OF THE FIRST AUTHORISATION

05 August 2011

10. DATE OF REVISION OF THE TEXT

July 2023

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Approved 28 July 2023