

Veterelin® 0.004 mg/ml



Solution for injection for cattle, pigs, horses and rabbits

Composition: Each ml contains: Active substance:

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

Excipient: Benzyl alcohol (E 1519) 10 mg, Sodium chloride, Sodium dihydrogen phosphate monohydrate, Sodium hydroxide, Water for injection.

Clear and colourless solution.

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

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 synchronization with an analogue of progestagen (altrenogest) in order to perform a single artificial insemination.

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

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.

For animal treatment only.

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:

UK(NI), GB: <https://www.gov.uk/report-veterinary-medicine-problem>

IE: HPRA Pharmacovigilance. Website: www.hpra.ie

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 |
| Sow (sexually mature gilt) | 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 rabbit 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.

Advice on correct administration: The vial can only be broached a maximum of 20 times.

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

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: 8 hours.

Special precautions for disposal: IE: 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.

UK(NI), GB: Medicines should not be disposed of via wastewater. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

Classification of veterinary medicinal products: Veterinary medicinal product subject to prescription.

Marketing authorisation numbers and pack sizes: IE: VPA10665/003/001; UK(NI): Vm 20634/3001; GB: Vm 20634/5003. Pack sizes: 1 x 10 ml vial; 1 x 20 ml vial; 5 x 10 ml vial. Not all pack sizes may be marketed.

Date on which the package leaflet was last revised: July 2023

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

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

Contact details:

Marketing authorisation holder and 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:

E.G.G. TECHNOLOGIES INTERNATIONAL LTD 18 Springfield Park, Tisbury, Salisbury, Wiltshire, SP3 6QN, UK Tel.: +44 (0) 1722 717478 E-mail: brian@eggtech.co.uk

Other information:

IE only

VPA 10665/003/001

POM

Prescription only Medicine

UK(NI), GB only

UK(NI): Vm 20634/3001

GB: Vm 20634/5003

POM-V

To be supplied only on veterinary prescription





Name: Veterelin

Packaging size:

115x240 mm

Pantones:

Pantone 2757 C

Pantone 032

Pantone 631C

Font Size (text):

8 pt

Packaging Reference:

Ref. 300872-004

Presentation:

leaflet

Last changes:

QRD

Date of last changes:

06/23

rights