Veteglan® 0.075 mg/ml



Ref. 302430-004

Solution for injection for cows, sows and mares

Composition: Each ml contains: **Active substance:** d-Cloprostenol 0.075 mg as d-Cloprostenol sodium salt 0.079 mg. **Excipient:** Citric acid, Chlorocresol 1.0 mg, Sodium hydroxide, Water for injections.

Clear and colourless aqueous solution.

Target species: Cattle (cows), pigs (sows) and horses (mares).

Indications for use: Cows: Synchronisation or induction of oestrus. Induction of parturition after day 270 of gestation. Treatment of ovarian dysfunction (persistent *corpus luteum*, luteal cyst). Treatment of clinical endometritis with the presence of a functional *corpus luteum* and pyometra. Induction of abortion up to day 150 of gestation. Expulsion of mummified foetuses. Delayed uterine involution. Therapy for the treatment of ovarian cysts (9-14 days after initial administration of GnRH or analogue).

Sows: Induction of parturition after day 114 of gestation.

Mares: Induction of luetolysis in mares with a functional *corpus luteum*.

Contraindications: Do not use in pregnant animals unless it is desirable to induce parturition or interruption of pregnancy. Do not use in animals with spastic dysfunctions of the gastrointestinal tract/or respiratory system. Do not use in cows or sows who may have a dystocic parturition due to abnormal position of a foetus, mechanical obstruction, etc.. Do not use in animals suffering cardiovascular or respiratory diseases. Do not use by intravenous route. Do not use in case of hypersensitivity to the active substance or to any of the excipients.

Special warnings: Special warnings: The response of cows to the synchronisation protocols is not homogeneous between herds, nor within the same herd, and may vary depending on the physiological state of the animal at the time of treatment (sensitivity and a functional state of the corpus luteum, age, physical condition, interval from calving, etc.). **Special precautions for safe use in the target species:** Induction of parturition and abortion may increase the risk of complications, retained placenta, foetal death and metritis. To reduce the risk of anaerobic infections, which might be related to the pharmacological properties of prostaglandins, care should be taken to avoid injection through contaminated areas of skin. Clean and disinfect injection sites thoroughly before administration.

In case of oestrus induction in cows: from the 2nd day after injection, adequate heat detection is necessary. Induction of parturition in sows before day 114 of gestation may result in an increased risk of stillbirths and the need for manual assistance at farrowing. **Special precautions to be taken by the person administering the veterinary medicinal product to animals:** Prostaglandins of the F2α type can be absorbed through the skin and may cause bronchospasm or miscarriage. Take care to avoid self-injection or skin contact when handling the product. Pregnant women, women of child-bearing age, asthmatics and people with bronchial or other respiratory problems, should avoid contact with, or wear disposable impervious gloves when administering the product. Accidental spillage on the skin should be washed off immediately with soap and water. In case of accidental self-injection or shortness of breath resulted from accidental inhalation or injection , seek medical advice and show the label to the physician. Do not eat, drink or smoke while handling the product. **Pregnancy and lactation:** Do not administer to pregnant animals unless it is desirable to induce parturition or interruption of pregnancy. **Interaction with other medicinal products and other forms of interaction:** Do not administer the treatment together with non-steroidal anti-inflammatory drugs since they inhibit endogenous prostaglandin synthesis. The activity of other oxytocic agents can be increased after the administration of cloprostenol. **Overdose:** At 10 times the therapeutic dose, no adverse reactions were reported. In general, a large overdose could result in the following symptoms: increased pulse and breathing rate, bronchoconstriction, increased body temperature, increased amounts of loose faeces and urine, salivation and vomiting. As no specific antidote has been identified, in the case of overdose, symptomatic therapy is advisable. In mares, moderate sweating and soft faeces were detected when the product was administered at 3 times the therapeutic dose. **Major incompatibilities:** In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Adverse events: Target species: Cows

Undetermined frequency
Injection site anaerobic infection (swelling and crepitus)[1]
Retained placenta[2]

[1]Anaerobic infection is common if anaerobic bacteria penetrate the tissue of the injection site. This applies especially to intramuscular injection and in particular to cows.

[2] Depending on the timing of treatment relative to the date of conception, the placental retention rate can be increased when used for induction of parturition.

CALIER - All rights reserved

CALIER

Target species: Sows

Undetermined frequency
Injection site anaerobic infection (swelling and crepitus)[1]
Retained placenta[2]
Behavioural changes[3]

1Anaerobic infection is common if anaerobic bacteria penetrate the tissue of the injection site. This applies especially to intramuscular injection and in particular to cows.

2 Depending on the timing of treatment relative to the date of conception, the placental retention rate can be increased when used for induction of parturition.

3 Behavioural changes seen after treatment for induction of farrowing, which are similar to those changes associated with natural farrowing and usually cease within 1 hour.

Target species: Mares

Undetermined frequency
Injection site anaerobic infections (swelling and crepitus)[1]
Retained placenta[2]
Sweating[3,4]
Increased respiratory rate[4]
Increased heart rate[4]
Abdominal discomfort[4], diarrhoea[4,5]
Depression[4]

[1]Anaerobic infection is common if anaerobic bacteria penetrate the tissue of the infection site. This applies especially to intramuscular injection and in particular to cows.

[2] Depending on the timing of treatment relative to the date of conception, the placental retention rate can be increased when used for induction of parturition.

[3] Ocurring within 20 minutes of treatment

[4] When exceptionally high doses are given and are usually mild and transient.

[5] Watery

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, 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: https://www.gov.uk/report-veterinary-medicine-problem. IE: www.HPRA.ie.

Dosage for each species, routes and method of administration: For intramuscular use.

Cows: 2 ml of the product / animal (equivalent to 150 µg d-Cloprostenol/animal)

Sows: 1 ml of the product / animal (equivalent to 75 µg d-Cloprostenol/animal)

Mares: 1 ml of the product / animal (equivalent to 75 µg d-Cloprostenol/animal)

Advice on correct administration: Cows:

Induction of oestrus **(also in cows showing weak or silent heat):** Administer the product after determination of the presence of a functional *corpus luteum* (6th to 18th day of cycle). Heat usually appears within 48-60 hours. Proceed to insemination 72 – 96 h after treatment. If there is no sign of oestrus, the treatment may be repeated 11 days after the first injection.

Induction of parturition: administer the product after the 270th day of gestation. Parturition usually takes place within 30 – 60 hours after treatment.

Synchronisation of oestrus: administer the product twice (within an interval of 11 days). Proceed with inseminations 72 h and 96 h after the second injection.

Ovarian dysfunction: administer the product after determination of presence of corpus luteum. Then proceed to inseminate at the first oestrus after injection. If oestrus does not take place, conduct a further gynaecological examination, and repeat the injection 11 days after the first administration. Insemination must always be carried out 72 – 96 hours after injection.

Clinical endometritis with the presence of a functional corpus luteum, pyometra: administer one dose of the product. If necessary, repeat the treatment after 10 days.

Mummified **foetus:** Administer one dose of the product. Expulsion of the foetus is observed within 3-4 days after the administration of the product.

Induction of abortion: Administer one dose of the product in the first half of pregnancy.

Delayed uterine involution: administer one dose of the product and, if needed, carry out one or two further treatments (within an interval of 24 hours).

Therapy for the treatment of ovarian cysts (9-14 days after initial administration of GnRH or analogue): administer the product 9-14 days after verifying the positive response to treatment with GnRH or analogue.

The rubber stopper of the vial can be safely punctured up to 10 times. Otherwise, for the 20 ml vials, automatic syringe equipment, or a suitable draw-off needle, should be used to prevent excessive puncture of the closure.

CALIER - All rights reserved

Withdrawal period: Cattle: meat and offal: zero days; milk: zero hours. Pigs: meat and offal: 1 day. Horses: meat and offal: 2 days; milk: zero hours.

Special storage precautions: Keep out of the sight and reach of children. Do not store above 25ºC. Keep the vial in the outer carton in order to protect from light. Do not use this medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that month. Shelf-life after first opening theimmediate packaging: 28 days.

Special precautions for the disposal: NI: 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. IE: Medicines should not be disposed of via wastewater or household waste. The veterinary medicinal product should not enter water courses as cloprostenol may be dangerous for fish and other aquatic organisms. 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.

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

Marketing authorisation numbers and package sizes: UK: Vm 20634/3002. IE: VPA 10665/008/001. 10 ml or 20 ml amber coloured Type I glass vials, with Teflon-coated chlorobutyl rubber closures and aluminium seals with blue coloured plastic flip-offs, packaged singly in a cardboard box. Cardboard box with 1 x 10 ml or 1 x 20 ml vials. Not all pack sizes may be marketed.

Date on which the package leaflet was last revised: December 2022. Detailed information on this veterinary medicinal product is available in the Union Product Database.

Contact details: Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions: Laboratorios Calier, S.A. C/Barcelonès, 26 Polígono Industrial El Ramassa, Les Franqueses del Vallès, 08520 Barcelona, Spain, Tel. +34 938495133, E-mail: pharmacovigilance@calier.es

Other information: The product contains dextrorotatory cloprostenol, a synthetic analogue of the prostaglandin F2α. D-cloprostenol, the dextrorotatory enantiomer, constitutes the biologically active component of the racemic cloprostenol molecule and results in an approximate 3.58-fold increase in activity. Administered in the luteal phase of the oestrus cycle, d-cloprostenol induces an acute decrease of luteinic receptors (LH) in the ovary, inducing regression of the corpus luteum (luteolysis) resulting in a sharp fall in progesterone levels. The increased release of follicle stimulating hormone (FSH), induces follicular maturation followed by signs of oestrus and ovulation. After intramuscular administration of 75 µg of d-cloprostenol to sows, the maximum concentration of d-cloprostenol in plasma was close to 2 µg/l and occurred between 30 and 80 minutes after injection. The half-life of elimination T1/2 β was estimated to be 3h 10 min. After intramuscular administration of 150 µg of d-cloprostenol / cow, the highest plasma concentration of d-cloprostenol was found at 90 minutes after injection (approximately 1.4 µg/l). The elimination half-life was estimated to be 1h 37 min.

CALIER © All rights reserved

IE Only
VPA 10665/008/001
POM Prescription Only Medicine

UK (NI) Only
Vm 20634/3002
POM-V

To be supplied only on veterinary prescription.

CALIER

FSC www.fsc.org MIX Paper | Supporting responsible forestry FSC® C015546