PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Individual Cardboard box for a 10 ml or 20 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VETEGLAN 0.075 mg/ml Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCE AND OTHER SUBSTANCES

Each ml contains:
Active substance
d-Cloprostenol.....……...0.075 mg
as d- Cloprostenol sodium salt.……...0.079 mg
Excipients:
Chlorocresol..... 1.0 mg

3. PACKAGE SIZE

10 ml
20 ml

4. TARGET SPECIES

Cattle (cows), pigs (sows) and horses (mares).

5. INDICATION(S)

6. ROUTE(S) OF ADMINISTRATION

Intramuscular use

7. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle:	meat and offal: zero days
	milk: zero hours
Pigs:	meat and offal: 1 day
Horses:	meat and offal: 2 days
	milk: zero hours

8. EXPIRY DATE

EXP {mm/yyyy}
Once opened use within 28 days.
Once opened use by …

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25ºC.
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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

14. MARKETING AUTHORISATION NUMBER

Vm 20634/5004

15. BATCH NUMBER

Lot (number)

16. SPECIAL WARNING(S), IF NECESSARY

Special warnings for each target species

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 use in animals:

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 seek medical advice and show the label to the physician.
Should shortness of breath result from accidental inhalation or injection, seek medical advice immediately and show the package leaflet or label to the physician.
Do not eat, drink or smoke while handling the product.

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM–V

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
Label for a 10 ml or 20 ml vial

1. NAME OF THE VETERINAY MEDICINAL PRODUCT

VETEGLAN 0.075 mg/ml Solution for Injection

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

0.075 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp {mm/yyyy}
Once opened use within 28 days

5. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSIS

10 ml
20 ml

6. ROUTE OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIOD(S)

Withdrawal periods:

Cattle:	meat and offal: zero days
	milk: zero hours
Pigs:	meat and offal: 1 day
Horses:	meat and offal: 2 days
	milk: zero hours

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VETEGLAN 0.075 mg/ml Solution for injection for cows, sows and mares.

2. COMPOSITION

Each ml contains:

Active substance
d- Cloprostenol.....0.075 mg
as d-Cloprostenol sodium salt.....0.079 mg

Excipient:
Chlorocresol.....1.0 mg

Clear and colourless aqueous solution.

3. TARGET SPECIES

Cattle (cows), pigs (sows) and horses (mares).

4. 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.

5. 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.

6. 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 seek medical advice and show the label to the physician.
Should shortness of breath result from accidental inhalation or injection, seek medical advice immediately and show the package leaflet or 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.

For animal treatment only.

7. 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.

Target species: Sows

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

[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.
[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 { https://www.gov.uk/report-veterinary-medicine-problem}.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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)

9. 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.

10. WITHDRAWAL PERIOD(S)

Cattle: meat and offal: zero days
milk: zero hours

Pigs: meat and offal: 1 day

Horses: meat and offal: 2 days
milk: zero hours

11. 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 the container: 28 days.
When the container is broached/opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL

Medicines should not be disposed of via wastewater. Any unused veterinary medicinal product or waste materials derived from such medicinal products should be disposed of in accordance with local requirements.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACKAGE SIZES

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.

Vm 20634/5004

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

December 2022

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

16. 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 (Pla del Ramassà)
08520 Les Franqueses del Vallès
(Barcelona) Spain
Info@calier.es

17. 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.

Approved 02 February 2023