PARTICULARS TO APPEAR ON THE OUTER PACKAGE (CARDBOARD CARTON)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VETEGLAN 0.075 mg/ml Solution for Injection for Cows, Sows and Mares

d-cloprostenol

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
d- Cloprostenol ..... ……0.075 mg
as d-Cloprostenol sodium salt……..… 0.079 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

10 ml
20 ml

5. TARGET SPECIES

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

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular use only.
Read the package leaflet before use.

8. 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

9. 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 F2a type can be absorbed through the skin and may cause bronchospasm or miscarriage.
Care should be taken when handling the product to avoid self-injection or skin contact.
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.

10. EXPIRY DATE

EXP {month/year}

Once opened, use within 28 days.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

CALIER PORTUGAL, S.A.
Centro Empresarial Sintra-Estoril II, Edif. C
SINTRA
PORTUGAL

LABORATORIOS CALIER, S.A.
C/ Barcelonès, 26 (Pla del Ramassa)
LES FRANQUESES DEL VALLÈS, (Barcelona) SPAIN

16. MARKETING AUTHORISATION NUMBER

Vm 20634/4010

17. MANUFACTURER’S BATCH NUMBER

Batch (number)

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS VIA ADHESIVE LABEL ON BOTTLE

1. NAME OF THE VETERINAY MEDICINAL PRODUCT

VETEGLAN 0.075 mg/ml Solution for Injection for Cows, Sows and Mares

d-cloprostenol

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

0.075 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml
20 ml

4. ROUTE(S) OF ADMINISTRATION

For intramuscular use only.

5. 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

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Once opened, use within 28 days

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET FOR:
VETEGLAN
0.075 mg/ml Solution for Injection
d-Cloprostenol
For Cows, Sows and Mares

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFERENT

Marketing authorisation holder and manufacturer responsible for batch release:

LABORATÓRIOS CALIER, S.A.
Barcelonès, 26 (Pla del Ramassa)
Les Franqueses del Vallès (Barcelona)
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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

Excipient:
Chlorocresol.....1.0 mg

Solution for injection
Clear and colourless aqueous solution.

4. INDICATION(S)

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 associated to 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. ADVERSE REACTIONS

Occurrence of anaerobic infection is common if anaerobic bacteria penetrate the issue of the injection site. This applies especially to intramuscular injection and in particular to cows. Typical local reactions due to anaerobic infection are swelling and crepitus at the injection site. When used for induction of parturition and depending on the moment of treatment relative to the date of conception, increase of placental retention rate can occur.
Behavioural changes in sows seen after treatment for induction of farrowing are similar to those changes associated with natural farrowing and usually cease within 1 hour.
Adverse reactions in horses including sweating (occurring within 20 minutes of treatment), increased respiratory and cardiac rates, signs of abdominal discomfort, watery diarrhoea and depression may occur when exceptionally high doses are given. However, adverse reactions are usually mild and transient.

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 inform your veterinary surgeon.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

7. TARGET SPECIES

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

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For intramuscular use only.

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

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 associated to 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.

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)

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.

9. ADVICE ON CORRECT ADMINISTRATION

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 carton and the vial. The expiry date refers to the last day of that month.
Shelf-life after first opening the container: 28 days.

12. SPECIAL WARNING(S)

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 (severity 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 product to animals:

Prostaglandins of the F2a type can be absorbed through the skin and may cause bronchospasm or miscarriage.
Care should be taken when handling the product to avoid self-injection or skin contact.
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 prostaglandins synthesis.
The activity of other oxytocic agents can be increased after the administration of cloprostenol.

Overdose (symptoms, emergency procedures, antidotes)
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. An overdose will not accelerate corpus luteum regression.
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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT FOR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2020

15. OTHER INFORMATION

Pack sizes: 10 ml and 20 ml.
Not all pack sizes may be marketed.

Approved 19 October 2020