1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dalmaprost 0.075 mg/ml solution for injection for cattle, pigs and horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
D-cloprostenol 0.075 mg
(equivalent to 0.079 mg of d-cloprostenol sodium)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Chlorocresol	1 mg
Sodium hydroxide	
Citric acid	
Ethanol (96 per cent)	
Water for injections	

Clear, colourless solution, with no visible particles.

3. CLINICAL INFORMATION

3.1. Target species

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

3.2. Indications for use for each target species

The veterinary medicinal product is indicated for:

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;
- Treatment of delayed uterine involution;
- Induction of abortion up to day 150 of gestation;
- Expulsion of mummified foetuses.

Sows:

- Induction of parturition after day 114 of gestation.

Mares:

- Induction of luteolysis with a functional *corpus luteum*.

3.3 Contraindications

Do not use in pregnant females, unless it is desirable to induce parturition or induction of abortion.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not administer to animals with cardiovascular, respiratory or gastrointestinal problems.
Do not administer to induce parturition in sows and cows with suspected dystocia due to mechanical obstruction or if problems are expected because of an abnormal position of the foetus.

3.4 Special warnings

The response of cows to the synchronization protocols is not homogenous nor between the herds, neither 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.).

3.5. Special precautions for use

Special precautions for safe use in 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. Care should be taken when handling the veterinary medicinal product to avoid self-injection or skin contact.

Pregnant women, women of child-bearing age, asthmatics and people with bronchial or other respiratory problems, should avoid contact when handling this veterinary medicinal product, or personal protective equipment consisting of disposable impervious-gloves should be worn when administering the veterinary medicinal product.
In case of accidental spillage onto skin, seek medical advice immediately and show the package leaflet or the label to the physician.
Accidental spillage on the skin should be washed off immediately with soap and water.
Should shortness of breath result from accidental inhalation or injection, seek medical advice and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse reactions

Cattle (cows):

Common (1 to 10 animals / 100 animals treated):	Injection site infection[1](Injection site swelling, Crepitus)
Undetermined frequency (cannot be estimated from the available data):	Retained placenta[2]

[1] Due to anaerobic infection, especially after intramuscular injection.
[2] May increase when used for induction of parturition and depending on the moment of treatment relative to the date of conception

Pigs (sows):

Common (1 to 10 animals / 100 animals treated):	Injection site infection[1](Injection site swelling, Crepitus)
Undetermined frequency (cannot be estimated from the available data):	Retained placenta[2] Behavioural disorder[3]

[1] Due to anaerobic infection, especially after intramuscular injection.
[2] May increase when used for induction of parturition and depending on the moment of treatment relative to the date of conception
[3] Observed after treatment for induction of farrowing. The changes are similar to those changes associated with natural farrowing and usually cease within 1 hour.

Horses (mares):

Common (1 to 10 animals / 100 animals treated):	Injection site infection[1](Injection site swelling, Crepitus)
Undetermined frequency (cannot be estimated from the available data):	Retained placenta[2] Increased sweating [3,4] Increased respiratory rate[4] Increased heart rate[4] Abdominal discomfort[4], Watery diarrhoea[4] Depression[4]

[1] Due to anaerobic infection, especially after intramuscular injection.
[2] May increase when used for induction of parturition and depending on the moment of treatment relative to the date of conception
[3] Occurring within 20 minutes of treatment.
[4] May occur when exceptionally high doses are given. However adverse reactions are usually mild and transient.

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 its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7. Use during pregnancy, lactation or lay

Pregnancy and lactation:

Do not administer to pregnant animals unless the objective is to terminate the pregnancy.
Can be used during lactation.

3.8. Interaction with other medicinal products and other forms of interaction

Do not administer the veterinary medicinal product together with nonsteroidal anti-inflammatory drugs since they inhibit endogenous prostaglandin synthesis. The activity of other oxytocic agents can be increased after the administration of the veterinary medicinal product.

3.9. Administration routes and dosage

Intramuscular use.

COWS:
Administer one dose (2 ml) per animal of veterinary medicinal product (equivalent to 150 µg of d-cloprostenol per animal):

- **Induction of oestrus** (also in cows showing weak or silent heat): administer one dose of the veterinary medicinal product after having established the presence of a *corpus luteum* (6th -18th day of the cycle).

Heat usually appears within 48-60 hours. Proceed with insemination 72-96 hours after injection. If oestrus is not evident, administration of the veterinary medicinal product needs to be repeated 11 days after the first injection.

- **Synchronisation of oestrus:** administer one dose of the veterinary medicinal product twice (with an interval of 11 days between each dose). Proceed therefore with two artificial inseminations at intervals of 72 and 96 hours from the second injection.
  D-cloprostenol may be used in combination with GnRH, with or without progesterone, in the protocols for synchronization of the ovulation (Ovsynch protocols). The responsible veterinarian shall decide the protocol to be used, basing on the objective of the treatment, and on the herd and animals to be treated. The following protocols have been evaluated and may be used:

  In cycling cows:
  - Day 0: inject GnRH (or analogous).
  - Day 7: inject d-cloprostenol (one dose of the veterinary medicinal product).
  - Day 9: inject GnRH (or analogous).
  - 16-24 hours later perform artificial insemination.

  Alternatively in cycling or not-cycling cows and heifers:
  - Day 0: insert the intravaginal device for progesterone delivery and inject GnRH (or analogous).
  - Day 7: remove the intravaginal device and inject d-cloprostenol (one dose of the veterinary medicinal product).
  - Day 9: inject GnRH (or analogous).
  - 16-24 hours later perform artificial insemination.

- **Induction of parturition:** administer one dose of the veterinary medicinal product. Birth usually occurs within 30-60 hours of treatment.

- **Ovarian dysfunction (persistent *corpus luteum*, luteal cyst)**: once a *corpus luteum* has been detected, administer one dose of the veterinary medicinal product and inseminate at the first oestrus after injection. If oestrus is not evident, conduct a further gynaecological examination, and repeat the injection 11 days after the first administration. Insemination must be carried out 72-96 hours after injection.

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

- **Delayed uterine involution**: administer one dose of the veterinary medicinal product and, if considered necessary, carry out one or two successive treatments at 24 hours intervals.

- **Induction of abortion**: administer one dose of the veterinary medicinal product in the first half of pregnancy.

- **Mummified foetus:** expulsion of the foetus is observed within 3-4 days after administration of one dose of the veterinary medicinal product.

MARES:
For the induction of luteolysis in mares with a functional *corpus luteum*: administer a single injection of 1 ml of veterinary medicinal product/animal (equivalent to 75 µg of d-cloprostenol).

SOWS:
For the **i**nduction of parturition in sows: administer 1 ml of the veterinary medicinal product, equivalent to 75 micrograms of d-cloprostenol/animal, by intramuscular route, not earlier than 114 days of pregnancy. The injection can be repeated after 6 hours.

The stopper of the vial can be safely punctured up to 20 times. Otherwise, for the 100 ml vials automatic syringe equipment, or a suitable draw-off needle, should be used to prevent excessive puncture of the closure.

3.10. Symptoms of overdose (and where applicable, emergency procedures and antidotes)

At 10 times the therapeutic dose, no adverse reactions were reported in cows and sows.
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 veterinary medicinal product was administered at 3 times the therapeutic dose.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QG02AD90

4.2 Pharmacodynamics

The veterinary medicinal product is a sterile aqueous solution containing dextrorotatory cloprostenol, a synthetic analogue of the prostaglandin F2α. The dextrorotatory enantiomer, d-cloprostenol, constitutes the biologically active (luteolytic) component of the racemic cloprostenol molecule. The veterinary medicinal product is approximately 3.5 times more active than similar veterinary medicinal products containing racemic cloprostenol, thus it can be administered at a proportionally lower dose level.
During the luteal phase of the oestrus cycle, d-cloprostenol induces a reduction of the number of receptors for luteinizing hormone (LH) in the ovary, which leads to a rapid regression of the *corpus luteum*.

4.3 Pharmacokinetics

In cows, the highest plasma concentration of d-cloprostenol was found at 90 minutes after injection (approximately 1.4 µg/l). Elimination half-life is 1 h 37 minutes.
In sows, the highest plasma concentration is reached within 30 - 80 minutes after the injection. The elimination half-life is approximately 3 h and 12 minutes.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:
- glass vials: 30 months;
- HDPE containers: 18 months.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Store below 25 °C.
Keep the vial in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

Colourless type I glass vial (2 ml), colourless type II glass vials (10 ml and 20 ml) and transparent high density polyethylene (HDPE) container (100 ml), closed with a chlorobutyl type I stopper coated with a fluoroplastic film and a flip-off aluminium collar, in a cardboard box.

Package sizes:
Cardboard box with 15 vials of 2 ml
Cardboard box with 60 vials of 2 ml
Cardboard box with 1 vial of 10 ml
Cardboard box with 1 vial of 20 ml
Cardboard box with 1 HDPE container of 100 ml

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as d-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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

FATRO S.p.A

7. MARKETING AUTHORISATION NUMBERS

VPA10836/009/001

8. DATE OF FIRST AUTHORISATION

13/09/2019

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

07/08/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database. (*https://medicines.health.europa.eu/veterinary*).