

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box 15 x 2 ml vials
60 x 2 ml vials
1 x 10 ml vial
1 x 20 ml vial
1 x 100 ml HDPE container

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF THE ACTIVE SUBSTANCES

Each ml contains d-cloprostenol 0.075 mg (equivalent to d-cloprostenol sodium 0.079 mg)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

15 x 2 ml
60 x 2 ml
1 x 10 ml
1 x 20 ml
1 x 100 ml

5. TARGET SPECIES

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

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use
Read the package leaflet before use

8. WITHDRAWAL PERIODS

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.

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use

10. EXPIRY DATE

EXP {month/year}

Shelf life after first broaching the immediate container: 28 days.

Once broached, use by _____

11. SPECIAL STORAGE CONDITIONS

Store below 25 °C.

Keep the vial in the outer carton in order to protect from light.

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

Disposal: read package leaflet.

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

Fatro S.p.A.

Via Emilia, 285

Ozzano dell'Emilia (BO)

Italy

16. MARKETING AUTHORISATION NUMBERS

Vm 11557/4006

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE
PACKAGING UNITS**

Label 2 ml, 10 ml, 20 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITY OF THE ACTIVE SUBSTANCE

d-cloprostenol 0.075 mg/ml

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

2 ml
10 ml
20 ml

4. ROUTE(S) ADMINISTRATION

IM

5. WITHDRAWAL PERIODS

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.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month /year}

Once opened, use by _____

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label 100 ml HDPE container

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dalmaprost 0.075 mg/ml, solution for injection for cattle, pigs and horses.
d-cloprostenol

2. STATEMENT OF THE ACTIVE SUBSTANCES

Each ml contains d-cloprostenol 0.075 mg (equivalent to d-cloprostenol sodium 0.079 mg)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

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

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

IM
Read the package leaflet before use

8. WITHDRAWAL PERIODS

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.

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use

10. EXPIRY DATE

EXP {month/year}

Shelf life after first broaching the immediate container: 28 days.

Once broached, use by _____

11. SPECIAL STORAGE CONDITIONS

Store below 25 °C.

Keep the vial in the outer carton in order to protect from light

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

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”

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Fatro S.p.A.
Via Emilia, 285
Ozzano dell'Emilia (BO)
Italy

16. MARKETING AUTHORISATION NUMBERS

Vm 11557/4006

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PACKAGE LEAFLET

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

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

Marketing authorisation holder and manufacturer responsible for batch release:

FATRO S.p.A. - Via Emilia, 285 – Ozzano dell'Emilia (Bologna), Italy

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Each ml contains:

Active substance:

d-cloprostenol.....0.075 mg
(equivalent to d-cloprostenol sodium.....0.079 mg)

Excipients:

chlorocresol.....1 mg

Clear, colourless solution, with no visible particles.

4. INDICATIONS

The 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*.

5. CONTRAINDICATIONS

Do not use in pregnant females, unless it is desirable to induce parturition or induction of abortion.

Do not use in case 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.

6. ADVERSE REACTIONS

Occurrence of 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. 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 observed 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

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)

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. Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

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

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

For intramuscular administration only.

COWS:

Administer one dose (2 ml) per animal of 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 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 product needs to be repeated 11 days after the first injection.
- **Synchronisation of oestrus:** administer one dose of the 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 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 product).
- Day 9: inject GnRH (or analogous).
- 16-24 hours later perform artificial insemination.

- **Induction of parturition:** administer one dose of the 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 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 product. If necessary, repeat the treatment after 10 days.
- **Delayed uterine involution:** administer one dose of the product and, if considered necessary, carry out one or two successive treatments at 24 hours intervals.

- **Induction of abortion:** administer one dose of the 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 product.

MARES:

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

SOWS:

For the induction 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 rubber 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.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. 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.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store below 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 container and the carton label 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 opened for the first time, the date on which any product remaining in the container should be discarded, should be worked out using the in-use shelf-life which is specified on this package leaflet. This discard date should be written in the space provided on the label.

12. SPECIAL WARNINGS

Special warnings for each target species

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.)

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 F2 α type can be absorbed through the skin and may cause bronchospasm or miscarriage.

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. Care should be taken when handling the product to avoid self-injection or skin contact.

In case of accidental spillage onto the skin, the area involved should be washed 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.

Use during pregnancy and lactation

Do not administer to pregnant animals unless the objective is to terminate the pregnancy.

The product can be used safely during lactation.

Interaction with other medicinal products and other forms of interaction

Do not administer the 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 product.

Overdose (symptoms, emergency procedures, 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 product was administered at 3 times the therapeutic dose.

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 OR WASTE MATERIALS, IF ANY

Medicine should not be disposed of via wastewater or household waste
Ask your veterinary surgeon how to dispose of medicine no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2021

15. OTHER INFORMATION

Package sizes:

- Box with 15 vials of 2 ml
- Box with 60 vials of 2 ml
- Box with 1 vial of 10 ml
- Box with 1 vial of 20 ml
- Box with 1 HDPE container of 100 ml

Not all pack sizes may be marketed.

Approved 22 July 2021

