PARTICULARS TO APPEAR ON THE OUTER PACKAGE
2 ml vial + syringe - fifteen 2 ml vials - sixty 2 ml vials - 10 ml vial
Ten 10 ml vials - 20 ml vial - five 20 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dalmazin, 75 micrograms/ml, solution for injection for cattle and pigs.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Active substance: d-cloprostenol 75 µg - **Excipient:** chlorocresol 1 mg

3. PACKAGE SIZE

2 ml + syringe
15 x 2 ml
60 x 2 ml
10 ml
10 x 10 ml
20 ml
5 x 20 ml

4. TARGET SPECIES

Cattle (cows) and pigs (sows and gilts).

5. INDICATION(S)

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6. ROUTES OF ADMINISTRATION

For intramuscular use.

7. WITHDRAWAL PERIODS

Meat and offal:
cattle Zero days
pigs 1 day

Milk: Zero hours

8. EXPIRY DATE

Exp. {mm/yyyy}
Shelf-life after first opening the immediate packaging: 28 days.
Once broached, use by_____

9. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton.

Do not store above 25 °C.

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

Fatro S.p.A
Via Emilia, 285
40064 Ozzano Emilia
Bologna
Italy

Distributed in the UK and Ireland by:
Duggan Veterinary Supplies Ltd.
Holycross, Thurles,
Co. Tipperary, E41A093, Ireland

14. MARKETING AUTHORISATION NUMBERS

Vm 11557/5003

15. BATCH NUMBER

Batch {number}

16. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

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

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

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V
To be supplied only on veterinary prescription.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS 2 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dalmazin, 75 micrograms/ml, solution for injection for cattle and pigs.

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

d-cloprostenol 75 µg/ml

3. BATCH NUMBER

Batch {number}

4. EXPIRY DATE

EXP {month/year}
Once broached, use by 28 days.

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

2 ml

6. ROUTE(S) OF ADMINISTRATION

For intramuscular use.

7. WITHDRAWAL PERIOD

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8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.
POM-V

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS 10 ml vial – 20 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dalmazin, 75 micrograms/ml, solution for injection for cattle and pigs.

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

d-cloprostenol 75 µg/ml

3. BATCH NUMBER

Batch {number}

4. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the immediate packaging: 28 days
Once broached, use by_____

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

10 ml
20 ml

6. ROUTE(S) OF ADMINISTRATION

For intramuscular use.

7. WITHDRAWAL PERIOD

Withdrawal periods:
Meat and offal:
cattle Zero days
pigs 1 day

Milk: Zero hours

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.
POM-V

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dalmazin, 75 micrograms/ml, solution for injection for cattle and pigs.

2. COMPOSITION

Each ml contains:
Active substance: d-cloprostenol 75 µg - **Excipient:** chlorocresol 1 mg

Clear, colourless solution with no visible particles.

3. TARGET SPECIES

Cattle (cows) and pigs (sows and gilts).

4. INDICATIONS FOR USE

Cows
Indications for reproduction: synchronization or induction of oestrus. Induction of parturition after day 270 of gestation.

Therapeutic indications: ovarian dysfunction (persistent corpus luteum, luteal cyst), endometritis/pyometra, delayed uterine involution, induction of abortion in the first half of pregnancy and expulsion of mummified foetuses.

Sows and gilts
Indications for reproduction: induction of parturition.

5. CONTRAINDICATIONS

Do not use in pregnant females, unless it is desirable to induce parturition or induction of abortion.
Do not use in sows which are expected to have a distocic parturition due to abnormal position of the foetus, mechanical obstruction, etc.
Do not use in animals suffering cardiovascular or respiratory diseases.
Do not use in animals with spastic diseases of the respiratory or gastrointestinal tract.

6. SPECIAL WARNING(S)

Special warnings for each target species

None.

Special precautions for use in animals

As with parenteral administration of any substance, basic antiseptic rules should be observed. The injection site must be thoroughly cleaned and disinfected in order to reduce the risk of infection with anaerobic bacteria.
Induction of labour before the 111th day of gestation may cause mortality in piglets and an

increase in the number of sows that require manual assistance.
Do not administer by intravenous route.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Prostaglandins of the $F_{2\alpha}$ 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 plastic 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 urgent medical advice and show the doctor this warning.
Do not eat, drink or smoke while handling the product.

Use during pregnancy, lactation or lay
Do not use in gestating animals unless it is desirable to induce parturition or therapeutic induction of abortion.

Interactions 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 (symptoms, emergency procedures, antidotes), if necessary
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.

Incompatibilities

None known.

7. ADVERSE EVENTS

Cattle (cows) and pigs (sows and gilts):

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site infection[a].

[a] Occurrence of anaerobic infection is likely 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.

Cattle (cows):

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Retained placenta[b].

[b] When used in cows for induction of parturition and dependent on the time of treatment relative to the date of conception, the incidence of retained placenta may be increased.

Pigs (sows and gilts):

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Behavioural disorders[c].

[c] Behavioural changes seen after treatment for induction of farrowing are similar to those changes associated with natural farrowing and usually cease within one hour.

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 or to the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system {national system details}.

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

Cows
Administer 2 ml of the veterinary medicinal product, equivalent to 150 micrograms of d-cloprostenol/animal by intramuscular route. Repeat after 11 days for the synchronisation of oestrus.
The dose of 2 ml equivalent to 150 micrograms of d-cloprostenol/animal by intramuscular route can be repeated for the induction of oestrus and for the treatment of ovarian dysfunction, endometritis/pyometra and delayed uterine involution.

In particular:

- Induction of oestrus (also in cows showing weak or silent heat): administer the veterinary medicinal product after having established the presence of a corpus luteum (6-18th day of the cycle); heat usually appears within 48-60 hours. Proceed, therefore, 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 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.
- Induction of parturition: administer the veterinary medicinal product after 270 days of pregnancy. Birth usually results within 30-60 hours of treatment.
- Mummified foetus: expulsion of the foetus is observed within 3-4 days after administration of the veterinary medicinal product.
- Induction of abortion: administer the veterinary medicinal product in the first half of pregnancy.
- Ovarian dysfunction (persistent corpus luteum, luteal cysts): administer the veterinary medicinal product, then proceed to 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 always be carried out 72-96 hours after injection.
- Endometritis, pyometra: administer the veterinary medicinal product. If necessary repeat the treatment after 10-11 days.
- Delayed uterine involution: administer the veterinary medicinal product and, if considered necessary, carry out one or two successive treatments at 24 hour intervals.

Sows and gilts
Administer 1 ml of the veterinary medicinal product, equivalent to 75 micrograms of d-cloprostenol/animal, by intramuscular route, not earlier than 112 days of pregnancy. Repeat after 6 hours. Alternatively, 20 hours after the initial dose of the veterinary medicinal product, a myometrial stimulant (oxytocin or carazolol) may be administered.
Following the protocol of the double administration, approximately 70-80% of the animals will give birth during the interval between 20 and 30 hours after the first administration.

9. ADVICE ON CORRECT ADMINISTRATION

As with every prostaglandin-based product, injection in contaminated skin areas is to be avoided in order to reduce the risk of infection with anaerobic bacteria.
The injection site must be thoroughly cleaned and disinfected before administration.

10. WITHDRAWAL PERIOD(S)

Meat and offal:

cattle	Zero days
pigs	1 day

Milk: Zero hours

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25°C.
Do not use after the expiry date which is stated on the 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 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 DISPOSAL

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

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Pack sizes:
2 ml + syringe
15 x 2 ml
60 x 2 ml
10 ml
10 x 10 ml
20 ml
5 x 20 ml

Not all pack sizes may be marketed.

Vm 11557/5003

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

June 2023

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

16. CONTACT DETAILS

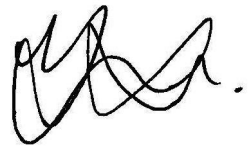
Marketing authorisation holder and manufacturer responsible for batch release:
Fatro S.p.A
Via Emilia, 285
40064 Ozzano Emilia
Bologna
Italy

Local representatives and contact details to report suspected adverse reactions:
Duggan Veterinary Supplies Ltd.
Holycross, Thurles,
Co. Tipperary, E41A093, Ireland

17. OTHER INFORMATION

Dalmazin is a sterile aqueous solution containing 75 micrograms/ml of dextrorotatory cloprostenol, a synthetic analogue of the prostaglandin $F_{2\alpha}$.
d-cloprostenol, the dextrorotatory enantiomer, constitutes the biologically active component of the racemic cloprostenol molecule and results in an approximate 3.5-fold increase in activity.
Administered in the luteal phase of the oestrus cycle, d-cloprostenol induces functional and morphological regression of the corpus luteum (luteolysis) resulting in a sharp fall in progesterone levels. The increased release of the follicle stimulating hormone (FSH), induces the follicular maturation followed by signs of oestrus and by ovulation.

Pharmacokinetic studies demonstrate a rapid absorption of d-cloprostenol. The peak blood level is reached a few minutes following intramuscular administration, as well as a rapid diffusion to the ovaries and uterus, the organs in which the maximum concentration is reached 10-20 minutes after administration.
Following intramuscular administration of 150 micrograms of d-cloprostenol in the cow, the peak plasma level (C_{max}) of 1.4 micrograms/l is reached after approximately 90 minutes, while the elimination half life ($t_{½\beta}$) is in the order of 1 hour 37 minutes. In sows, a C_{max} of approximately 2 micrograms/l is observed between 30 and 80 minutes following administration of 75 micrograms d-cloprostenol, with an elimination half life in the order of 3 hours 10 minutes.



Approved: 02 June 2023