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 (ES, IE, IT, PL, SI, UK).
Dalmazin SYNCH 0.075 mg/ml solution for injection for cattle, pigs and horses (AT, BE, BG, CY, CZ, DE, DK, EE, EL, HR, HU, IS, LT, LU, LV, MT, NL, PT, RO, SK)
Reprostenol SYNCH 0.075 mg/ml solution for injection for cattle, pigs and horses (FR)
Dalmaprost vet 0.075 mg/ml solution for injection for cattle, pigs and horses (FI, NO, SE)

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

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 (ES, IE, IT, PL, SI, UK)
Dalmazin SYNCH 0.075 mg/ml solution for injection for cattle, pigs and horses (AT, BE, BG, CY, CZ, DE, DK, EE, EL, HR, HU, IS, LT, LU, LV, MT, NL, PT, RO, SK)
Reprostenol SYNCH 0.075 mg/ml solution for injection for cattle, pigs and horses (FR)
Dalmaprost vet 0.075 mg/ml solution for injection for cattle, pigs and horses (FI, NO, SE)

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. (ES, IE, IT, PL, SI, UK)
Dalmazin SYNCH 0.075 mg/ml solution for injection for cattle, pigs and horses (AT, BE, BG, CY, CZ, DE, DK, EE, EL, HR, HU, IS, LT, LU, LV, MT, NL, NO, PT, RO, SK)
Reprostenol SYNCH 0.075 mg/ml solution for injection for cattle, pigs and horses (FR)
Dalmaprost vet 0.075 mg/ml solution for injection for cattle, pigs and horses (FI, NO, SE)

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

17. MANUFACTURER'S BATCH NUMBER

Batch {number}