

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1 vial of 10 ml
10 vials of 10 ml
1 vial of 20 ml
10 vials of 20 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GESTAVET-PROST 75 µg/ml , solution for injection.
Dexcloprostenol

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Composition per ml:

Active substance

Dexcloprostenol (sodium salt).....75 µg

Excipients

Chlorocresol

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

1 vial of 10 ml
10 vials of 10 ml
1 vial of 20 ml
10 vials of 20 ml

5. TARGET SPECIES

Cows and sows.

6. INDICATION(S)

Cows and heifers:

Treatment of:

- Anoestrus periods after parturition,
- Luteinic cysts
- Persistent corpus luteum
- Synchronisation and induction of heat
- Supportive treatment in chronic endometritis and pyometra
- Induction of abortion

Sows:

- Induction of parturition

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Bovine and porcine: Meat and offal: 1 day
Milk: Zero hours

9. SPECIAL WARNING(S), IF NECESSARY

The veterinary medicinal product must not be handled by pregnant women, asthmatic people or people with bronchial or other respiratory diseases. Avoid contact with eyes. In case of accidental contact, wash with abundant water. Avoid contact with skin. In case of accidental contact, wash immediately the affected area with abundant water.

Read the package leaflet before use.

10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2 °C – 8 °C).
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 veterinary medicinal product 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 REACH AND SIGHT OF CHILDREN”

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

BIOGÉNESIS GLOBAL, S.L.
Calle Quintanadueñas, 6. Bloque A 1ª planta.
28050 Madrid
Spain

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL

10 ml

20 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GESTAVET-PROST 75 µg/ml solution for injection.
Dexcloprostenol

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Quantity of the active substance per ml:
Dexcloprostenol (sodium salt) 75 g

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

10 ml

20 ml

4. ROUTE(S) OF ADMINISTRATION

By intramuscular route.

5. WITHDRAWAL PERIOD

Bovine and porcine: Meat and offal: 1 day
Milk: Zero hours

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Once broached, use by 28 days.
Date of first opening:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.