

## **LABELLING AND PACKAGE LEAFLET**

## **B. PACKAGE LEAFLET**

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

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

LABORATORIOS HIPRA, S.A.  
Avda. la Selva, 135  
17170 Amer (Girona)  
SPAIN

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

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

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)**

Composition per ml:

**Active substance**

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

**Excipients**

Chlorocresol

**4. 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

## **5. CONTRAINDICATIONS**

Do not use:

- In gestating animals unless abortion (in cows) or induction of labour (in sows) is the desired objective.
- As a supportive treatment in chronic endometritis and pyometra if the cycle blockade caused by pathological corpus luteum has not been diagnosed.
- In sows which are expected to have a distocic parturition due to abnormal position of the foetus, mechanical obstruction, etc.
- In animals suffering cardiovascular or respiratory diseases.
- By intravenous route.

## **6. ADVERSE REACTIONS**

No side effects have been observed in the treated animals.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

## **7. TARGET SPECIES**

Cows and sows.

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

By intramuscular route.

### **Cows and heifers:**

#### Synchronisation and induction of heat

2 ml of Gestavet-Prost per animal (equivalent to 150 µg dextroprostenol per animal), twice, within 11 days.

In order to obtain better results, the insemination should be conducted at the first heat after the treatment. Two inseminations (72 and 96 hours after the second application) are needed if heat detection is not performed.

#### Anoestrus periods after parturition

2 ml of Gestavet-Prost per animal (equivalent to 150 µg dextroprostenol per animal).

Before administration the animals should be checked for the presence of a corpus luteum by rectal palpation. Animals coming into heat should be inseminated. In animals not showing symptoms of heat, the administration of the product should be repeated after 11 days and insemination performed 72 and 96 hours after the second administration.

#### Supportive treatment in chronic endometritis and pyometra

2 ml of Gestavet-Prost per animal (equivalent to 150 µg dextroprostenol per animal).

In some cases, it may be necessary to administer a second dose, 10 to 12 days later.

#### Luteinic cysts

2 ml of Gestavet-Prost per animal (equivalent to 150 µg dextroprostenol per animal).

The presence of ovarian luteinic cysts should be confirmed.

Persistent corpus luteum

2 ml of Gestavet-Prost per animal (equivalent to 150 µg dextroprostenol per animal).  
The presence of persistent corpus luteum should be confirmed.

Induction of abortion

2 ml of Gestavet-Prost per animal (equivalent to 150 µg dextroprostenol per animal).  
The product should be administered between first week and 150<sup>th</sup> day of pregnancy. Manual extraction of the foetus may be necessary.

**Sows:**

Induction of parturition

1 ml of Gestavet-Prost per animal (equivalent to 75 µg dextroprostenol per animal).  
The treatment should be performed 1 to 3 days before the due date of farrowing.

**9. ADVICE ON CORRECT ADMINISTRATION**

- Induction of labour before the 111<sup>th</sup> day of gestation may cause mortality in piglets and an increase in the number of sows that require manual assistance.

**10. WITHDRAWAL PERIOD**

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

**11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the reach and sight of children.  
Store in a refrigerator (2 °C – 8 °C)  
Keep the vial in the outer carton in order to protect from light.  
Do not use after the expiry date stated on the label.  
Once broached, use by 28 days.

**12. SPECIAL WARNING(S)**

- The veterinary medicinal product must not be handled by pregnant women, asthmatics 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, immediately wash the affected area with abundant water.
- In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

**13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

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

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

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**15. OTHER INFORMATION**

Pack sizes:

10 ml vial

20 ml vial

10 x 10 ml vials

10 x 20 ml vials

Not all pack sizes may be marketed.