SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GESTAVET-PROST 75 µg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance:
Dexcloprostenol (sodium salt) …….75 µg
Excipients:
Chlorocresol .....1 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear, almost colourless liquid

4. CLINICAL PARTICULARS

4.1 Target species

Cows and sows.

4.2 Indications for use, specifying the target species

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

4.3 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.

4.4 Special warnings <for each target species>

None known.

4.5 Special precautions for use

Special precautions for use in animals
- 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
- 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.

4.6 Adverse reactions (frequency and seriousness)

No side effects have been observed in the treated animals.

4.7 Use during pregnancy, lactation or lay

Do not administer to pregnant animals if the abortion is not the desired effect.

4.8 Interaction with other medicinal products and other forms of interaction

The concomitant administration of progesterone or prostaglandins inhibitors -such as NSAID – can decrease or even abolish the effect of dexcloprostenol.

The concomitant administration with oxitocin potenciates the effect in uterus.

4.9 Amounts to be administered and administration route

By intramuscular route.

Cows and heifers:

Synchronisation and induction of heat
2 ml of Gestavet-Prost per animal (equivalent to 150 µg dexcloprostenol 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 dexcloprostenol 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 dexcloprostenol 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 dexcloprostenol 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 dexcloprostenol 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 dexcloprostenol per animal).
The product should be administered between first week and 150th 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 dexcloprostenol per animal).
The treatment should be performed 1 to 3 days before the due date of farrowing.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No adverse reactions were reported after the administration of a three-fold dose.

4.11 Withdrawal period(s)

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

5. PHARMACOLOGICAL PROPERTIES

Dexcloprostenol belongs to the pharmacoterapeutic group: Prostaglandins.
ATCvet code: QG02AD90

5.1 Pharmacodynamic properties

Dexcloprostenol is the dextrarotatory analogue of cloprostenol, a functional analogue of prostaglandin F_2. Its administration at the luteal phase of the cycle induces corpus luteum regression, and creates the preconditions for the beginning of the physiological functions associated to the decrease of the progesterone levels.

Different clinical studies have shown that dexcloprostenol is three to four times more potent that cloprostenol (racemic mixture). One injection of dexcloprostenol from the 7^{th} day of the oestral cycle to the natural luteolysis produces the immediate regression of the corpus luteum.

The mechanism of action of dexcloprostenol in the control of ovulation is based on the luteolysis induction and the decrease in the progesterone concentrations. That decrease produces a sequence of hormonal events that culminates with ovulation. Also, dexcloprostenol can induce parturition.

5.2 Pharmacokinetic particulars

After intramuscular administration of 75 g of dexcloprostenol to sows, the maximum concentration of dexcloprostenol in plasma (2 g/l) are reached between 30 and 80 minutes after injection. After intramuscular administration of 150 g of dexcloprostenol/cow, maximum plasma concentrations of dexcloprostenol (approximately 1.4 g/l) are reached at 90 minutes after injection.

Dexcloprostenol and its metabolites are excreted rapidly, with the urine and also with faeces. Less than the 0.75 % of the dose administered is eliminated with milk and there is no persistence of residues in tissues.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid monohydrate
Sodium hydroxide
Chlorocresol
Isopropyl alcohol
Water for injections.

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after first opening the immediate packaging: 28 days.

6.4. Special precautions for storage

Store in a refrigerator (2 °C – 8 ºC).
Keep the vial in the outer carton in order to protect from light.

6.5 Nature and composition of immediate packaging

The veterinary medicinal product is filled in 10 ml and 20 ml Type I glass vials, closed with an elastomer closure type I and anodised aluminium capsule.
Secondary package: cardboard box

Also clinical pack size is available: 10 glass vials of 10 ml in a cardboard box and 10 glass vials of 20 ml in a cardboard box.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

11/10/2006

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.