Product Monograph Information

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estroPLAN® injection

cloprostenol 250 g/mL (as cloprostenol sodium BP)
An analogue of prostaglandin F2- for intramuscular injection in cattle.
Sterile, Veterinary Use Only
DIN: 02298406

ACTIVE INGREDIENT
Each mL of estroPLAN contains 263 g of cloprostenol sodium, equivalent to 250 g of cloprostenol, in an isotonic citric acid buffer containing the antimicrobial preservative chlorocresol 0.1%w/v.

INDICATIONS
For intramuscular use to induce luteolysis in cattle. The luteolytic action of estroPLAN can be utilized to manipulate the estrous cycle to better fit certain management practices, to terminate pregnancies resulting from mismating and to treat certain conditions associated with prolonged luteal function.

THERAPEUTIC INDICATIONS
estroPLAN can be used in the following clinical situations:
Unobserved or non-detected estrus (in cows with normal corpora lutea)
Cows may be cycling but either fail to display behavioural estrus or display only very subtle signs. This condition occurs most commonly in high yielding dairy cows at peak lactation. The presence of ovarian cyclical activity should be determined by rectal palpation of a normal corpus luteum prior to estroPLAN administration. Estrus should commence 2 - 5 days following treatment. Failure of estrus induction may result if the treatment is given during the refractory period of the corpus luteum. Treated animals should be inseminated at the usual time following detection of estrus or, if estrus detection is not practiced, inseminated twice at 72 and 96 hours post injection.

Pyometra or Chronic Endometritis
Damage to the reproductive tract at calving or postpartum retention of the placenta often leads to infection and inflammation of the uterus (endometritis). Under certain circumstances, this may progress into chronic endometritis with the uterus becoming distended with purulent matter. This condition, commonly referred to as pyometra, is characterized by a lack of cyclical estrus behaviour and the presence of a persistent corpus luteum. Induction of luteolysis with estroPLAN usually results in evacuation of the uterus and a return to normal cyclical activity. Where necessary, treatment may be repeated after 10 - 14 days.

Termination of pregnancies from mismating, abortion in feedlot heifers
Unwanted pregnancy can be terminated by treatment with estroPLAN from about one week after mating until about 4½ months of gestation. The induced abortion is normally uncomplicated and the fetus and placenta are usually expelled about 4 - 5 days after injection with the reproductive tract returning to normal soon after the abortion. Treated animals should be closely observed until expulsion of the fetus

and placental membranes is complete. The ability of estroPLAN to induce abortion decreases beyond 4½ months of gestation while the risk of dystocia and its complications increases.

Termination of abnormal pregnancy: mummied fetus
Fetal death may result in the mummification of the fetus in utero. Treatment with estroPLAN at any stage of gestation will usually result in luteolysis and expulsion of the mummified fetus from the uterus. Occasionally manual removal of the fetus from the vagina is necessary. Normal cyclical activity usually follows.

Controlled breeding
estroPLAN can be used in a number of treatment regimens to synchronize the estrous cycle and ovulation of groups of cows. Cloprostenol induces luteolysis of functional corpora lutea, with estrus occurring in most cows in 2 - 5 days. However, it should be noted that the corpus luteum is refractory to the effects of PG in the first 4 - 5 days before and after ovulation.

estroPLAN can be incorporated into a controlled breeding program as follows:

1. Single estroPLAN injection
Only animals with a mature corpus luteum should be treated. The presence of an anatomically normal, nonpregnant reproductive tract, ovarian cyclical activity and the presence of a mature corpus luteum should be determined by rectal palpation prior to estroPLAN administration. If these criteria are met, estrus is expected to occur 2 - 5 days following injection, at which time animals may be inseminated. Treated animals should be inseminated at the usual time following detection of estrus or, if estrus detection is not practiced, inseminated twice at 72 and 96 hours post-injection.

With a single injection program it may be desirable to assess the cyclicity status of the herd before estroPLAN treatment. This can be accomplished by heat detecting and breeding at the usual time following detection of estrus for a six day period, all prior to injection. If by the sixth day the cyclicity status appears normal (approximately 25 - 30% detected in estrus) all cattle not already inseminated should be palpated for normality, non-pregnancy, and cyclicity, then injected with estroPLAN.

2. Double estroPLAN injections
The presence of an anatomically normal, non-pregnant reproductive tract and ovarian cyclical activity should be determined by rectal palpation prior to administration of the first estroPLAN injection. A second injection of estroPLAN should be given 11 days following the first injection. In normal cycling animals estrus is expected to occur 2 - 5 days following the second injection. Treated animals should be inseminated at the usual time following detection of estrus or, if estrus detection is not practiced, inseminated twice at 72 and 96 hours post injection.

Many animals will come into estrus following the first injection. Those animals can be inseminated at the usual time following detected estrus. Animals not inseminated should receive a second injection 11 days after the first injection.

Any controlled breeding program recommended should be completed by either:

- Observing animals (especially during the third week after injection) and inseminating or hand mating any animals returning to estrus, or
- Turning in clean-up bull(s) 7 - 8 days after the last injection of estroPLAN to cover any animals returning to estrus

Requirements for controlled breeding programs
A variety of programs can be designed to best meet the needs of individual management systems. A controlled breeding program should be selected which is appropriate for the existing circumstances and management practices.

Before a controlled breeding program is planned the producer's objectives must be examined and he must be made aware of the projected results and limitations. The producer and his consulting veterinarian

should review the operation's breeding history, herd health and nutritional status and agree that a controlled breeding program is practical in the producer's specific situation.

To achieve good results with planned mating programs, several key factors must be given adequate consideration:

- A high proportion of cows in the herd need to be cycling normally, as PGs are only effective in cows with mature corpora lutea. This may not be the case in herds in which there are many first calvers, late calvers or cows in poor condition.
- Cows must be in a fit and healthy breeding condition and on an adequate or increasing plane of nutrition. Animals in poor or medium condition should be fed to ensure a positive nutritional balance for 4 - 6 weeks before estroPLAN treatment and for 4 weeks after treatment.
- Proper program planning and record keeping are essential.
- Estrus detection needs to be of a high standard.
- If artificial insemination is being used, a competent technician using high-quality semen must perform insemination.

Provision must be made to supervise the calving of a large number of cattle over a short period of time.

DOSAGE AND ADMINISTRATION
Only cattle with a functional CL can respond to the luteolytic action of estroPLAN. In the cycling animal there are refractory periods of 4 to 5 days before and after ovulation when cattle are not responsive to PGs.

For therapeutic indications and controlled breeding: 2 mL estroPLAN injection by intramuscular injection.

For abortion: 1.5 mL (2 mL for animals over 455 kg) by intramuscular injection.

CONTRAINDICATIONS
Do not administer estroPLAN to pregnant animals whose calf is not to be aborted.

CAUTIONS
To reduce the risk of anaerobic infections care should be taken to avoid injection through contaminated areas of skin. Clean and disinfect injection sites thoroughly before application.

WARNINGS
Treated animals must not be slaughtered for human consumption for at least twenty-four (24) hours after the latest treatment with this drug. No milk withholding time is required in cattle when used according to label.

This product should be handled **carefully to avoid accidental self-injection or contact with the skin or mucous membranes of the user.**

Prostaglandins of the F2α type may be absorbed through the skin and may cause bronchospasms and/or miscarriage.

Pregnant women, women of childbearing age, asthmatics and people with other respiratory tract diseases should exercise extreme caution when handling this product such as wearing waterproof gloves.

Accidental spillage on the skin should be washed off immediately with water.

In case of accidental self-injection, seek medical advice and show the package insert to the doctor. Should respiratory distress result from accidental inhalation or injection, the inhalation of a rapidly acting bronchodilator is indicated.

Keep out of reach of children.

ADVERSE REACTIONS
As with other products in this class, when used for induction of parturition, the incidence of retained placenta may be increased depending on the time of treatment.

A low incidence of clostridial and other infections at the injection site has been reported following prostaglandin administration. Treated animals should be closely observed post-injection and appropriate antibiotic therapy initiated at the first sign(s) of infection.

Very rarely, anaphylactic reactions have occurred after the administration of the product.

Overdose: At 50 and 100 times the recommended dose of cloprostenol mild side e-ects may be detected. These included increased uneasiness, mild transient diarrhea, slight frothing and milk letdown.

ACTION
estroPLAN causes rapid regression of the functional corpus luteum in cattle. In non-pregnant cycling cattle luteolysis is usually followed by ovarian follicular development and a return to estrus with normal ovulation in 2 - 5 days after treatment. The early corpus luteum is insensitive to the e-ects of prostaglandin (PG); in cattle this refractory period spans the first 4 - 5 days before and after ovulation. In animals with prolonged luteal function (pyometra, mummified fetus) the induced luteolysis usually results in resolution of the condition and return to cyclicity. Pregnant animals may abort depending on the stage of gestation.

STORAGE
Store below 25°C. Protect from light: store in product carton.

Presentation:
20 mL, 50 mL and 100 mL multidose vials

Product Code:
900088 (20 mL), 900089 (50 mL), 900090 (100 mL)