Pr

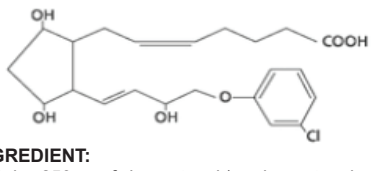
CLOPROSTENOL VEYX™

(Cloprostenol Injection, B.P. Vet - 250µg/mL)

3308 4 CA - V01.17

DIN 02418037
Sterile Synthetic Prostaglandin Analogue for Cattle.
For veterinary use only.

DESCRIPTION:
Cloprostenol (Cloprostenol Veyx™) is a synthetic prostaglandin analogue, structurally related to prostaglandin F_2 (PGF_2).



ACTIVE INGREDIENT:
Each ml contains 250 µg of cloprostenol (as cloprostenol sodium) in an isotonic citrate buffer

PRESERVATIVE:
0.1% w/v chlorocresol B.P.

NONMEDICINAL INGREDIENTS:
Each mL contains:

Citric acid, monohydrate	2mg	Sodium chloride	8mg
Trisodium citrate, dihydrate	5mg	Sodium hydroxide 20% (g/V)	q.s.
Water for injection	q.s.		

INDICATIONS:
By its ability to shorten the life span of the *corpus luteum* Cloprostenol Veyx™ can be used to treat certain clinical conditions which delay breeding, to manipulate the estrous cycle to better fit certain management practices, and to induce abortion.

Sub-estrus (silent heat or non-detected estrus):
Cows which fail to exhibit normal estrous behaviour although ovarian cyclicity continues can be treated with Cloprostenol Veyx™ while in the luteal phase of the estrous cycle. They may then either be closely observed for estrus over a scheduled time period and bred on detection of estrus or bred at 72 and 96 hours after injection without estrus detection.

Pyometra or chronic endometritis:
Damage to the reproductive tract at calving or postpartum retention of the placenta frequently leads to infection and inflammation of the uterus which is usually referred to as endometritis. Under certain circumstances, this may progress into chronic endometritis with the uterus becoming distended with purulent matter. This condition, frequently referred to as pyometra, is characterized by lack of cyclical estrous behaviour and the presence of a persistent *corpus luteum.* This condition can be successfully treated by causing regression of the C.L. by treatment with Cloprostenol Veyx™. Where necessary, treatment may be repeated after 10-14 days.

Pregnancies from mis-mating and abortion in feedlot heifers:
Unwanted pregnancies can be safely and efficiently terminated from one week after mating until about 4 1/2 months of gestation. The induced abortion is uncomplicated, the fetus and placenta are usually expelled about 4 or 5 days after the injection and the reproductive tract returns to normal soon after the abortion. Trial results have demonstrated that an abortion rate of approximately 95% can be expected up to 4 1/2 months of gestation. The ability of Cloprostenol Veyx™ to induce abortion decreases beyond 4 1/2 months while the risk of dystocia and its consequences increases.

Mummified fetus:
Death of the conceptus during gestation may be followed by its degeneration and dehydration. Induction of luteolysis with Cloprostenol Veyx™ usually results in the expulsion of the mummified fetus from the uterus.
(Manual assistance may be necessary to remove the fetus from the vagina. Normal cyclical activity should then follow.)

CONTROLLED BREEDING:
The luteolytic action of Cloprostenol Veyx™ can be used to schedule estrus and ovulation for an individual animal or a group of animals. This allows control of the time at which cycling cows or heifers can be bred.

DOSAGE AND ADMINISTRATION:
Cloprostenol Veyx™ should be administered by INTRAMUSCULAR INJECTION. Only cattle with functional C.L. can respond to the luteolytic action of Cloprostenol Veyx™. In the cycling animal there are refractory periods of 4 to 5 days before and after ovulation when cattle are not responding to prostaglandin.

For Therapeutic Indications - 2 mL
For Controlled Breeding - 2 mL
For Abortion - 1.5 mL (2 mL for animals over 455 kg)

Injection Regimens:
For abortion and for therapeutic indications - one injection. For controlled breeding - Veterinarians and their client dairy and beef producers should select the controlled breeding program (A, B, or C) which is appropriate for the existing circumstances and management practices.

Manufactured for:
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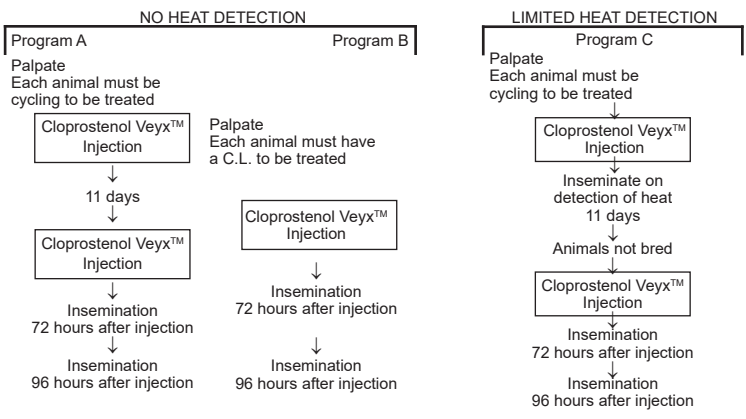

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First service conception rates in Canada using existing artificial insemination practices are generally agreed to be between 40% and 60% for beef cattle and 50% to 60% for dairy cattle. The spread of calf crops indicates similar levels are attained using natural service. Field trial results have demonstrated that producers can achieve similar conception rates using cloprostenol (as cloprostenol sodium). If existing management breeding practices are resulting in higher or lower conception rates, similar levels can be expected using cloprostenol (as cloprostenol sodium). Following the controlled breeding program those animals not conceiving should be rebred. This may be done by:
- observing animals for a return to estrus (especially during the third week after injection) and inseminating or hand mating animals returning to estrus, or
- turning in clean-up bull(s) 7 to 8 days after the last injection to cover any animal returning to estrus.

Many factors affect conception rates. Before a controlled breeding program is planned, 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. For a successful controlled breeding program:
- Cows and heifers must be cycling. Cattle should be palpated.
- Cattle should be in good condition for breeding. Animals in poor or medium condition should be fed to ensure a positive nutritional balance for 4-6 weeks before Cloprostenol Veyx™ treatment and for 4 weeks after treatment.
- Proper program planning and record keeping are essential;
- Artificial insemination must be performed by competent inseminators using high quality semen. Inseminator fatigue must be avoided.

CONTRA-INDICATIONS:
Since cloprostenol results in an abortion rate of approximately 95% in cattle up to 4 1/2 months of gestation and causes some cattle in later pregnancy to abort, it should not be given to pregnant animal unless induced abortion is desired.

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 cattle must not be slaughtered for use in food for at least 48 hours after the latest treatment with this drug. No withholding time is required for milk when used according to the 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 $F_{2\alpha}$ type may readily be absorbed through the skin and may cause bronchospasms and/or miscarriage.
Pregnant women, women in 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 occured after administration of the product.

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

ACTION:
Cloprostenol Veyx™ causes functional and morphological regression of the *corpus luteum* in cattle. This effect on the life span of the C.L. usually results in estrus two to five days after treatment, followed by ovulation with normal fertility. Cloprostenol Veyx™ alone will not increase fertility.

STORAGE:
Store at controlled room temperature 15-30 °C. Protect from light. Discard any remainder 28 days after initial broaching.

HOW SUPPLIED:
Vials of 10 mL, 20mL and 50mL

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