

RESTRICTED VETERINARY MEDICINE

Keep out of reach of children

FOR ANIMAL TREATMENT ONLY

Estrumate[®]

PROSTAGLANDIN

50mL

Read the entire label and leaflet before use

ACTIVE: Contains 250µg cloprostenol (as 263µg cloprostenol sodium) per mL of aqueous solution. The solution also contains 0.1%w/v chlorocresol as a bactericide.

DESCRIPTION:

Estrumate, a synthetic prostaglandin, is a potent luteolytic agent for use in cattle and horses. Cloprostenol is structurally related to Prostaglandin F_{2α} (PGF_{2α}). Both cause functional and morphological regression of the corpus luteum (luteolysis). Luteolysis is usually followed by a return to oestrus 2 to 4 days after treatment (with normal ovulation). Estrumate is specific in its luteolytic action, it is ineffective when there is not a corpus luteum present. For example, there is a refractory period of 5 to 6 days after ovulation when animals are insensitive to the luteolytic effect of prostaglandins. Estrumate has a wide safety margin. There is no deleterious effect on progeny conceived at the oestrus resulting from treatment with Estrumate.

ESTRUMATE IN CATTLE

The life cycle of the corpus luteum (CL) is terminated by the release of the uterine luteolysin. Thus an exogenous luteolytic agent such as Estrumate can effectively shorten the cycle length, provided it is administered at times when a fully functional corpus luteum is present. There are short periods in the cycle when the system is insensitive. These are the periods directly preceding and directly following oestrus. That is, the 4 to 5 day period in the late luteal/early follicular phase when the old corpus luteum is regressing and the 5 to 6 day period after ovulation when the new corpus luteum is developing. Between these periods there is a 12 day period when the fully functional corpus luteum will respond to Estrumate.

Controlled Breeding Programmes

Before a programme is planned, the farmer and veterinarian should discuss the expected results and limitations of the programme, reviewing the herd's breeding history, herd health and nutritional status to decide if it is practical in the particular circumstances.

For any successful controlled breeding programme using prostaglandins:

- Cows and heifers must be normal, non-pregnant and cycling (an examination should be performed)
- Cattle must be in good breeding condition and on an adequate or increasing plane of nutrition.
- Proper programme planning and record keeping are essential (animals must be identified).
- If artificial insemination is used it must be performed by competent inseminators using **high quality** semen.
- Oestrus observation is
- important; this is greatly assisted by use of tail paint.
- It is important to understand that Estrumate is effective only in animals with mature corpus luteum (ovulation must have occurred at least 5 days prior to treatment).

Cattle which respond to a single prostaglandin injection will normally do so within 6 days of treatment. Please refer to Estrumate publications for options on different programmes.

Therapeutic uses

Several reproductive problems in cattle associated with luteal function will respond to luteolytic treatment with Estrumate. A single dose of Estrumate is likely to be highly effective in the following circumstances:

• Sub-oestrus (or non-detected oestrus, or silent heat)

Sub-oestrus is that condition when the animal shows no clinical signs of heat but in fact normal cyclic ovarian activity is present. If rectal palpation indicates a corpus luteum on the ovary, the cow will usually respond to a 2mL injection of Estrumate by displaying heat 2 to 5 days later. Animals treated in the refractory period of the cycle will not respond. Animals not showing heat should be examined first, they may have lapsed into anoestrus. If it is appropriate they should receive a second Estrumate injection 11 days after the first and be inseminated 72 and 96 hours later whether observed in oestrus or not.

• Termination of early pregnancy

Pregnancy can be terminated from one week after conception until the 150th day of gestation. Before 100 days gestation, abortion can be induced rapidly and efficiently, but between 100 and 150 days of gestation results are less reliable. Treated animals should be kept under supervision until the foetus and foetal membranes are expelled. An occasional animal may develop metritis following abortion. Most cows will abort in 3 to 5 days, if an animal has not aborted by the 12th day a second Estrumate injection should be given.

• Termination of abnormal pregnancy

1. Removal of mummified foetus

If the corpus luteum is present, induction of Luteolysis with Estrumate will result in the expulsion of the foetal remains into the vagina in 3 to 5 days.

2. Abnormal conditions near parturition

- Vaginal prolapse: Recurring vaginal prolapse can be a problem in late pregnancy which can be treated with Estrumate (2mL i/m) to induce parturition.
- Hydrops of foetal membranes: Pathological accumulation of placental fluids, hydramnios or hydrallantois can cause severe physiological complications or death. A single injection of Estrumate usually results in the presentation of a live calf in late pregnancy. Success has been achieved as early as the 6th month of pregnancy.

• Chronic purulent endometritis (pyometra)

This condition may be successfully treated with a single dose. Acute or sub-acute endometritis may require both local and systemic antibiotic treatment. However, induction of luteal regression by treatment with Estrumate usually results in evacuation of the uterus in 3 to 4 days allowing antibiotic treatment. Occasionally some cases with extreme endometrial damage may require 2 or even 3 treatments with Estrumate at 10 day intervals.

• Luteal Cysts

Estrumate has proven effective in correcting the condition and bringing about a return of cycling 2 to 4 days later. Rectal palpation 7 to 10 days later should reveal whether regression is complete. Accurate diagnosis is essential if completely satisfactory results are to be achieved.

• Induction of parturition

Estrumate may be used in a planned calving programme as a 2mL dose 7 to 12 days after depot corticosteroid. All treated animals must receive adequate supervision. Induction closer to the predicted calving date is more likely to maximise calf survival because of reduced viability of the very premature calf. After day 270 of gestation (excluding *Bubalus* spp. and *Bos indicus* where the normal gestation is longer) cows treated with Estrumate usually calve within 48 hours. However the range can extend from less than 24 hours up to one week.

Common side effects of induction:

- Retained foetal membranes
- Calf mortality
- Pre-partum oestrus

DOSAGE AND ADMINISTRATION IN CATTLE

Care should be taken to avoid injection through wet or dirty areas of skin. Single or repeat doses of 2mL (500µg cloprostenol) administered by intramuscular or subcutaneous injection in the anterior half of the neck.

ESTRUMATE IN HORSES

The property of shortening the life span of the corpus luteum enables Estrumate to be highly effective in certain conditions in the horse. It is useful for treating aberrant cycles and for efficient stud management.

Induction of luteolysis following early foetal death and resorption

8 to 10% of all mares that conceive can lose the conceptus during the first 100 days of pregnancy. This loss is frequently diagnosed during routine examination. These mares do not return to oestrus for many weeks due to persistence of luteal function.

If the condition is not recognised and treated, valuable time can be lost, sometimes an entire breeding season. In such cases Estrumate can be used to induce luteolysis which should be followed by oestrus and ovulation. Treatment before day 45 is recommended, since after this time the presence of circulating progesterone from other sources may inhibit any response.

Termination of persistent dioestrus

Mares treated with Estrumate during dioestrus will show heat 2 to 4 days later, with ovulation occurring about 8 to 12 days after treatment.

Termination of pseudopregnancy

Mares showing this condition should respond well to treatment with Estrumate and will return to normal oestrus behaviour and ovulation.

Treatment of lactational anoestrus

Treatment with Estrumate should produce normal oestrus behaviour and ovulation. (This situation is analogous to prolonged dioestrus in nonpregnant mares which are not lactating).

Establishing oestrous cycles in barren and maiden mares

These mares may be found to have a functional corpus luteum and be either suffering from abnormal persistence of luteal function (prolonged dioestrus) or simply failing to exhibit normal oestrous behaviour ("silent heat") while ovarian cycles continue. These mares respond to treatment with Estrumate.

DOSAGE AND ADMINISTRATION IN HORSES

Care should be taken to avoid injection through wet or dirty areas of skin. Single dose of 0.5 to 1 mL for mares up to 400kg bodyweight, and 1 to 2mL for mares 400kg bodyweight and above, administered by intramuscular injection in the anterior half of the neck.

CONTRAINDICATIONS IN HORSES

Adverse reactions in horses including sweating (occurring within 20 minutes of treatment), increased respiratory and cardiac rates, signs of abdominal discomfort, watery diarrhoea and depression may occur when exceptionally high doses are given. However adverse reactions are usually mild and transient. This product should NOT be administered to:

- Mares suffering from acute or sub-acute disorders of the gastro-intestinal tract.
- Mares suffering from acute or sub-acute respiratory disease (This is a precautionary measure because in some species of animals, dosing with prostaglandins can result in acute respiratory distress).
- Pregnant mares, since luteolysis at some stages of gestation will result in loss of the foetus.

ESTRUMATE IN PIGS

In contrast to the situation in cattle and horses, the porcine corpus luteum is less sensitive to exogenous prostaglandins, which therefore have no direct practical application in the breeding management of non-pregnant sows and gilts. Cloprostenol has been widely evaluated for use in planned farrowing and can be recommended for the induction of farrowing in sows and gilts. A single dose is given 1 to 2 days before expected farrowing date. Farrowing can be expected to commence within 36 hours, the majority (75%) starting between 19 and 29 hours after injection.

DOSAGE AND ADMINISTRATION IN PIGS

Care should be taken to avoid injection through wet or dirty areas of skin. A single dose of 0.7mL is administered by intramuscular injection in the anterior half of the neck

CONTRAINDICATIONS

Do not administer to pregnant animals unless the objective is to terminate the pregnancy. Do not administer i/v.

WITHHOLDING PERIOD - Nil

STORAGE

Store away from light, below 30°C. After first opening, the product may be stored at or below 30°C for up to 28 days.

HANDLING PRECAUTIONS

Direct contact with skin or mucous membranes of the user should be avoided. Prostaglandins of the F2 α type may be absorbed through the skin and may cause bronchospasm or miscarriage. Care should be taken when handling the product to AVOID SELF-INJECTION OR SKIN CONTACT. Pregnant women, women of childbearing age, asthmatics and persons with other respiratory tract diseases should exercise caution when handling cloprostenol. Those persons should avoid contact or wear disposable gloves during administration of the product. Accidental spillage on the skin should be washed immediately with soap and water. The possible incidence of bronchospasm with the product is unknown.

FIRST AID

Should shortness of breath result from accidental inhalation or injection, seek urgent medical advice and show this warning. For advice contact the National Poisons Centre 0800 POISON (0800 764 766) or a doctor.

DISPOSAL

Dispose of unused contents in a suitable landfill. Dispose of empty container by puncturing and burying in a suitable landfill, or if appropriate recycle

See *Safety Data Sheet for further information*. www.msd-animal-health.co.nz

ACVM Registration No: A2698

See www.foodsafety.govt.nz for registration conditions.

Registered pursuant to the HSNO Act 1996, HSR002169

See www.epa.govt.nz for controls

ESTRUMATE is a registered trademark. © 2013

Registered to:

Schering-Plough Animal Health Limited

Phone: 0800 800 543

www.msd-animal-health.co.nz