

R_x Cloprostenol Sodium Injection I.P. Vet Estrumate®

232994 R2



NOT FOR HUMAN USE; FOR ANIMAL TREATMENT ONLY

**SCHEDULE H PRESCRIPTION DRUG – CAUTION Not to be sold by retail
without the prescription of a Registered Veterinary Practitioner only**

DESCRIPTION

Estrumate, a synthetic prostaglandin analogue for use in cattle and horses is structurally related to prostaglandin F_{2α} (PGF_{2α})

COMPOSITION:

Each ml contains:

Cloprostenol Sodium 263µg (equivalent to 250 µg Cloprostenol)
Benzyl alcohol 20 mg

INDICATION FOR USE

Synthetic Prostaglandin analogue for therapeutic use and for control of estrus cycle.

Cattle:

(A) Controlled breeding (estrus synchronization)

(B) Therapeutic indications

- Treatment of non-detected estrus associated with a functioning or persistent corpus luteum (absence of heat in the first 90 days post-partum)
- Treatment of chronic endometritis / pyometra associated with a functioning or persistent corpus luteum
- Treatment of ovarian luteal cysts
- Induction of parturition
- Termination of pregnancy

Horses:

(A) Controlled breeding (as an aid to stud management)

(B) Therapeutic indications

- Induction of luteolysis in case of prolonged diestrus or “pseudopregnancy”
- Induction of luteolysis following early foetal death and resorption (during the first 40 days of pregnancy)
- Establishing visible estrus cycles in case of “silent heat” in barren / maiden or in early post-partum mares

DOSE AND ADMINISTRATION

Cattle

Single or repeated doses of 2 mL Estrumate (equivalent to 500 µg cloprostenol) administered by intramuscular injection.

(A) Controlled breeding (estrus synchronization)

Control of the oestrous cycle is of value in:

- 1) In a group of females which are mostly cycling (usually the dairy herds): prostaglandin based treatments and GnRH/prostaglandins based treatments can be used successfully to synchronize estrus and facilitate reproductive management.
- 2) In a group of females which are mostly non-cycling (usually the beef herds): protocols based on prostaglandins combined with other tools (progestagens/progesterone releasing devices) should be preferred.

Examples of protocols that have been used:

Two injections 11 days apart

Breed any animals showing estrus before the second injection, either on signs of estrus or at fixed times (see special warnings). The second dose may be given only to those cattle not seen in estrus during that time and is followed by breeding either on signs of estrus or at fixed times (see special warnings).

In combination with GnRH analogues

- a) “Ovsynch” protocol: GnRH is administered on day 0, a prostaglandin injection is given on day 7 and an additional GnRH injection on day 9. A single fixed-time artificial insemination may be done between approximately 12-24 hours after the last GnRH injection.
- b) “Co-Synch” protocol: same as “Ovsynch” with insemination given together with the second GnRH injection on day 9.

In combination with progesterone/progesterone releasing devices

As treatment duration with these devices is usually shorter than normal luteal phase, a prostaglandin injection - usually 48 hours before removing the device - is necessary.

(B) Therapeutic indications

Treatment of non-detected estrus associated with a functioning or persistent corpus luteum (absence of heat in the first 90 days post-partum)

After diagnosing the presence of a corpus luteum – by rectal palpation – treat with the product and inseminate those animals showing heat. Those animals that do not show heat should be re-examined 11 days later and may receive a second injection and be bred at detected estrus or inseminated twice at 72 and 96 hours (see special warnings).

Treatment of chronic endometritis / pyometra associated with a functioning or persistent corpus luteum

Estrumate may be used as a part of treatment for chronic endometritis when an active corpus luteum is present at the time of treatment. Treat with a single dose. In long-standing cases, treatment may be repeated after 10-14 days.

Treatment of ovarian luteal cysts

Where luteal cysts are detected together with lack of estrus, Estrumate is effective in triggering cyst regression and return to cyclicity.

Induction of parturition

Estrumate can induce parturition when administered around normal term. Induction should take place as close to the predicted calving date as possible and not more than 10 days before.

Induction should not be attempted before day 270 of gestation measured from the confirmed day of conception, except in pathological conditions. All treated animals must receive adequate supervision. A higher than usual incidence of retention of the foetal membranes is to be expected as observed with all parturition induction treatments.

Termination of pregnancy

Normal pregnancy can be terminated in cattle from one week after conception until the day 150 of gestation. Best results are obtained during the first 100 days. Treated animals should be carefully monitored until expulsion of the foetus and placenta is complete. In case of a pathological pregnancy (mummified foetus, hydrops of the foetal membrane), abortion can be attempted at any stage of gestation. Manual removal of foetus and/or foetal membranes may be necessary.

Horses

Ponies and donkeys: Single or repeated doses of 0.5-1.0 mL Estrumate (equivalent to 125- 250 µg cloprostenol) administered by intramuscular injection.

Thoroughbreds, hunters and heavy horses: Single or repeated doses of 1-2 mL Estrumate (equivalent to 250-500 µg cloprostenol) administered by intramuscular injection.

(A) Controlled breeding (as an aid to stud management)

Estrus may be synchronized in groups of mares, allowing breeding at pre-determined times, to facilitate more efficient use and management of stallions and/or semen during the breeding season. In case of embryonic transfer (ET), it is also necessary to synchronize recipients with donors. Estrus usually starts within 3 to 4 days after Estrumate administration.

Examples of protocols that have been used:

Single Estrumate administration

When breeding at the second estrus after foaling is desired, a single dose of Estrumate may be administered 6 to 8 days after the ovulation of the “foal heat” in order to hasten the occurrence of the second estrus. Similarly, when the last ovulation date is known, a single dose of Estrumate can be used to synchronize and time estrus.

Two Estrumate administrations 14-18 days apart

The injection of two doses of Estrumate 14-18 days apart triggers synchronization of estrus in a group of mares. This method has value when a group of mares needs to be synchronized for breeding or for embryonic transfer.

In combination with progesterone/progestagen based programs

A single dose of Estrumate needs to be administered on the last day of progestagen treatment (8 days long) in order to ensure luteolysis in all mares. Once estrus is detected and large follicles are present, hCG may be injected to trigger ovulation.

(B) Therapeutic indications

Estrumate can be used effectively for the treatment of conditions associated with a functioning or persistent corpus luteum, such as:

Induction of luteolysis in case of prolonged diestrus or “pseudopregnancy”

Some mares, following mating or insemination develop a persistent corpus luteum despite not being pregnant. These animals are said to be “pseudopregnant”. Similarly, towards the end of the breeding season (early summer), mares frequently and spontaneously display persistent corpora lutea generating prolonged diestrus. Estrumate induces the regression of the persistent corpus luteum and results in return to estrus.

Induction of luteolysis following early foetal death and resorption (during the first 40 days of pregnancy)

About 8 to 10 percent of mares which conceive lose the conceptus during the first 40 days of pregnancy. As soon as pregnancy loss is diagnosed, prostaglandins such as cloprostenol may be injected to hasten re-breeding.

Establishing visible estrus cycles in case of “silent heat” in barren/maiden or in early postpartum mares

In these cases, some mares (owing to the presence of a foal or because they have not been previously exposed to a stallion) may not display estrus signs despite the observation of a corpus luteum. If Estrumate is used to induce the regression of the existing corpus luteum, a new opportunity to detect estrus will be given to the breeder/stud master.

SPECIAL WARNINGS:

Cattle

Cattle which respond to a single prostaglandin injection will normally do so within 6 days of treatment. The response time after two injections is less variable. Animals may be inseminated on detection of estrus or possibly given two fixed time insemination at 72 and 96 hours after the second injection. If animals are still in heat at 96h, an additional artificial insemination can be given. If a single fixed time artificial insemination is intended, prostaglandins should preferably be combined with GnRH (Ov-Synch or Co-Synch protocol) or progesterone/progestagen releasing devices.

Attention should be directed to the diet and condition of the treated animals. Sudden changes in feeding levels, in feed constituents and in housing, etc should be avoided around the time of the breeding program, as should any other factor, such as regrouping, which could reasonably be expected to lead to stress.

Special precautions for use

Special precautions for use in animals

For successful treatment, animals should be cycling. Administration of Estrumate when the existing corpora lutea are over 5 days of age is a prerequisite for treatment's efficacy. A proper check of the ovaries (by rectal examination or ultrasonography) before treatment will avoid the treatment failures linked to non-cycling animals.

Due to the possibility of post-injection bacterial infections, careful aseptic techniques should be employed. Do not administer intravenously.

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

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 in childbearing age, asthmatics and persons with other respiratory tract diseases should exercise caution when handling Estrumate. 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. Should shortness of breath result from accidental inhalation or injection, seek urgent medical advice and show the doctor this warning.

ADVICE ON CORRECT ADMINISTRATION

Due to possibility of post-injection bacterial infection, careful aseptic techniques should be employed.

WITHDRAWAL PERIOD

Zero days.

CONTRAINDICATIONS

Do not use in pregnant animals unless the objective is to terminate the pregnancy.

Do not use in animals with spastic disease of the respiratory or gastrointestinal tract.

ADVERSE REACTIONS

When use for indication for parturition and dependent on the time of treatment relative to the date of conception, the incidence of retained placenta may be increased.

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

PRECAUTIONS

- Do not administer intravenously.
- Estrumate can be absorbed through the skin and therefore care should be taken when handling the product, especially by women of child bearing age and by the asthmatics.
- Do not mix with other medicinal product. Incompatibilities with strong acid/alkaline product.

STORAGE CONDITIONS

Keep out of the reach and sight of children

Store below 30 °C, protected from light.

In order to protect from light keep the vials in outer carton

Do not use after expiry date stated on the carton

SHELF LIFE:

Shelf Life of Product: 24 months

Shelf life after first broaching of the vial: 4 weeks

PRESENTATIONS

Multidose vials containing 10/20/50/100 ml

MANUFACTURED BY:

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