C-PROST™ INJECTION

ACTIVE CONSTITUENT: 250µg/mL CLOPROSTENOL (as the sodium salt)

Potent partner for breeding programs

For luteolysis of functional corpora lutea in cows and mares.

- Induces luteolysis of functional corpora lutea
- Causes regression of the corpus luteum in mares
- Improves reproduction performance
- Use as part of a reproduction program in conjunction with G-RELIN™ Injection (GnRH)
- Rapidly distributed
- NIL milk WHP

	C-PROST™	OVUPROST®
Active Constituent	250 µg/ml CLOPROSTENOL (as the sodium salt)	250 µg/ml CLOPROSTENOL (as the sodium salt)
Species	Cattle and Horses	Cattle and Horses
Route of Administration	IM Injection	IM Injection
Dose rate		
Cattle	2mL	2mL
Horses	<400kg: 0.5-1mL >400kg: 1-2mL	<400kg: 0.5-1mL >400kg: 1-2mL
Witholding periods		
Meat (cattle)	1 day	1 day
Milk (cattle)	Zero Days	Zero Days
ESI	Not established	Not established

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For luteolysis of functional corpora lutea in cows and mares

INDICATIONS

COWS

Cloprostenol induces luteolysis of functional corpora lutea, with return to oestrus in most cows in 2-4 days. The corpus luteum is refractory to the effects of PG in the first 4-5 days post ovulation. Conception rates at the induced and subsequent oestrus periods are normal, and there are no detrimental effects on calves conceived following PG treatment.

C-PROST™ Injection can be used in the following clinical situations:

1. Synchronisation of the oestrus cycle for controlled breeding

Cloprostenol Injection alone can be used in a number of treatment regimes to synchronise the oestrus cycle of groups of cows including*:

- **Double Prostaglandin Program**
- **Why Wait Program**
- **Modified Why Wait Programs**
- **PGF2α + GnRH Programs**

**Please see label for full instructions on controlled breeding programs*

2. Routine use in the early postpartum period to improve reproductive performance

Routine treatment with cloprostenol in the early postpartum period can reduce the calving to conception interval in dairy herds. A number of factors are thought to be involved in this response: the myometrial stimulatory effect of PG resulting in more rapid uterine involution. a sparing effect on uterine infection; and the luteal effect providing more prompt treatment of cows with sub or silent oestrus or prolonged luteal phases. One or two treatments can be given between 12- and 40-days post-partum.

3. Unobserved oestrus in cows with normal corpora lutea

Cows may be cycling normally, but either fail to display behavioural oestrus or display only very subtle signs. This condition occurs most commonly in high yielding dairy cows at peak lactation. Normal ovarian cyclical activity should be determined by rectal palpation of a corpus luteum prior to C-PROST™ Injection administration. Oestrus should commence 2-4 days following treatment, with artificial insemination of joining at the detected heat. Failure of oestrus indication may result if the treatment is given during the refractory period of the corpus luteum and will necessitate a further injection 14 days after the first.

4. Termination of unwanted normal pregnancies (e.g. following misalliance)

Pregnancy can be terminated by treatment with C-PROST™ Injection from 7-150 days following conception. Between days 7-100, abortion is rapidly and reliably induced within 3-5 days of treatment. Between days 100-150, results may be less reliable due to the decreasing role of luteal progesterone and increasing role of placental progesterone in the maintenance of pregnancy. If abortion has not occurred by the eighth day following treatment, a repeat injection should be given. Treated animals should be closely observed until expulsion of the foetus and placental membranes is complete. Abortion should not be induced with C-PROST™ Injection alone after day 150 of gestation.

5. Termination of abnormal pregnancy (e.g. expulsion of mummified foetuses)

Foetal death my result in the mummification of the foetus in utero. Treatment with C-PROST™ Injection at any stage of gestation will result in luteolysis and expulsion of the mummified foetus from the uterus. Occasionally manual removal of the foetus from the vagina is necessary.

Pathological accumulation of placental fluids (hydramnios or hydrallantois) can be a life-threatening condition and is rarely resolved by surgical drainage. Termination of pregnancy by C-PROST™ Injection is often the preferred treatment option.

6. Induction of parturition

Parturition may be induced using C-PROST™ Injection but to optimise calf viability should be carried out as close to the predicted calving date as possible and should not be attempted prior to day 270 of gestation. Parturition usually occurs between 36-48 hours following treatment with C-PROST™ Injection. All cows so induced should be closely supervised. As with all other methods used to induce parturition there may be a higher than usual incidence of retained foetal membranes. Any reduction in survival rates of calves born as a result of parturition induction is considered to be a result of prematurity rather than an effect attributable to PG treatment.

7. Retained foetal membranes, pyometra or chronic endometritis

Cloprostenol has a stimulatory effect on the myometrium causing uterine contraction. This action can aid in the expulsion of retained foetal membranes. In the absence of septicaemia C-PROST™ Injection may aid in the treatment of post-partum uterine infections via regression of the corpus luteum and stimulation of the myometrial contractions. The rapid decline in progesterone and increase in oestrogen, which occur as a result of luteolysis, stimulates uterine defence mechanisms and further aids in resolution of infection.

8. Luteal cysts

Cystic ovaries may be associated with persistent luteal tissue and treatment with cloprostenol may effectively resolve such conditions and allow a return to normal cyclical activity.

MARES

Cloprostenol causes regression of the corpus luteum in mares except during the refractory period spanning the first 4-5 days after ovulation. Oestrus commences 2-5 days following cloprostenol administration, with normal ovulation occurring 8-12 days after treatment. Conception rates at the induced oestrus are normal, and there are no deleterious effects on foals born as a result of cycle manipulation. C-PROST™ Injection may be of clinical value in the following situations:

1. Unobserved or undetected oestrus (silent heat) in mares cycling normally

Mares cycling normally may not display full behavioural oestrus or other physiological changes commonly associated with oestrus (e.g. oedema and relaxation of the cervix), resulting in failure to observe optimal covering times. This condition has a higher incidence in maiden mares early in the breeding season. Rectal palpation or ultrasound aids in the diagnosis of normal cyclical activity. Treatment with C-PROST™ Injection enables prediction of the time of onset of oestrus, allowing optimum utilisation of teasing and stallion resources.

2. Prolonged dioestrus

Prolonged dioestrus due to the presence of persistent corpora luteum occurs in up to 20% or mares and responds to a single injection of C-PROST™ Injection.

3. Early foetal death followed by resorption

Early foetal death (in the first 100 days) occurs in up to 8-10% of mares and may be followed by foetal resorption and a failure to return to cyclical activity due to the presence of persistent corpora lutea. C-PROST™ Injection administration may be useful in the treatment of this condition.

4. Pseudopregnancy

Mares with a persistent corpus luteum may display signs of pregnancy but be found to be non-pregnant on examination. Treatment with C-PROST™ Injection should induce luteolysis and a return to normal cyclical activity.

5. Lactation – related anoestrus

Lactational anoestrus occurs relatively commonly, particularly in mares which foal early in the breeding season. Affected mares may or may not ovulate at the "foal heat" but thereafter fail to return to oestrus, often for several months. C-PROST™ Injection may be effective in inducing a return to normal cyclical activity, although results are variable.

6. Induction of abortion prior to day 45 (e.g. following misalliance)

Abortion may be induced by treatment with a single injection of cloprostenol prior to day 45 following conception. Following the formation of the endometrial cups at day 45 treatment with a single injection of PG may fail to induce abortion, and C-PROST™ Injection must be administered at daily intervals for 4 days to induce abortion in such mares. Mares in which abortion is induced after day 45 do not return to oestrus until the endometrial cups cease functioning.

7. Nomination of time of service

C-PROST™ Injection may be employed to bring mares into oestrus at nominated times, for the optimal management of high demand stallions during the breeding season.

8. Synchronisation of oestrus cycles

C-PROST™ Injection may be employed to synchronise the cycles of a group of mares, for example donor and recipient mares used in embryo transfer programmes.

DIRECTIONS FOR USE

Restraints

NOT TO BE USED in horses intended for human consumption.

Contraindications

Contraindicated for use in pregnant animals when abortion or induced parturition is not the objective. Contraindicated for intravenous administration. Contraindicated for use in mares suffering from acute or subacute disorders of the gastrointestinal or respiratory system.

Side Effects

Occasional side effects have been observed following intramuscular administration of PGs. Such effects are generally transient and have little detrimental effect on the animal. In cattle, increased body temperature and salivary secretion has been reported, usually associated with the administration of 5-10 times the recommended dose. Experimental administration of 50-100 times the recommended dose to cattle resulted in signs of uneasiness, salivation and milk let down, but no other adverse effects. In mares, sweating, increased respiratory and heart rates, ataxia, watery diarrhoea and signs of mild abdominal pain have been observed. Such reactions have usually resulted from doses in excess of that recommended and are generally mild and transient.

DOSAGE AND ADMINISTRATION

Use within 28 days of broaching the vial. Discard the unused portion.

Cows: single or repeat doses of 2 mL by intramuscular injection in the anterior half of the neck.

Mares: less than 400 kg bodyweight: 0.5-1 mL by intramuscular injection, Greater than 400 kg bodyweight: 1-2 mL by intramuscular injection.

General Directions

MODE OF ACTION

Cloprostenol is rapidly distributed in the body following intramuscular administration. In cattle maximum tissue levels are reached within 30 minutes of dosing. Cloprostenol is eliminated in approximately equal amounts via the kidney and in bile. Excretion in urine is partly as unchanged cloprostenol and partly as its tetranor acid, both in conjugated and unconjugated form.

In cattle, cloprostenol has a biological half-life of 1.6 hours. Within 24 hours the concentration of cloprostenol at the injection site falls below the limits of detection. Cloprostenol does not accumulate in the mammary gland.

WITHHOLDING PERIODS

MEAT (COWS): 1 day

MILK: Zero (0) days.

MEAT WITHHOLDING PERIOD (HORSES): DO NOT USE in horses that may be used for human consumption.

TRADE ADVICE

EXPORT SLAUGHTER INTERVAL (ESI): An ESI has not been established for this product.

SAFETY DIRECTIONS

Repeated exposure may cause allergic disorders. Wash hands after use.

FIRST AID

If poisoning occurs, contact a doctor or Poisons Information Centre, Phone Australia 131 126.

DISPOSAL

Dispose of container by wrapping with paper and putting in garbage.

STORAGE

Store below 25 °C (air conditioning). Protect from light.

APVMA Approval Number: 92624/136038

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