ELANCO ARTWORK LEGEND V16

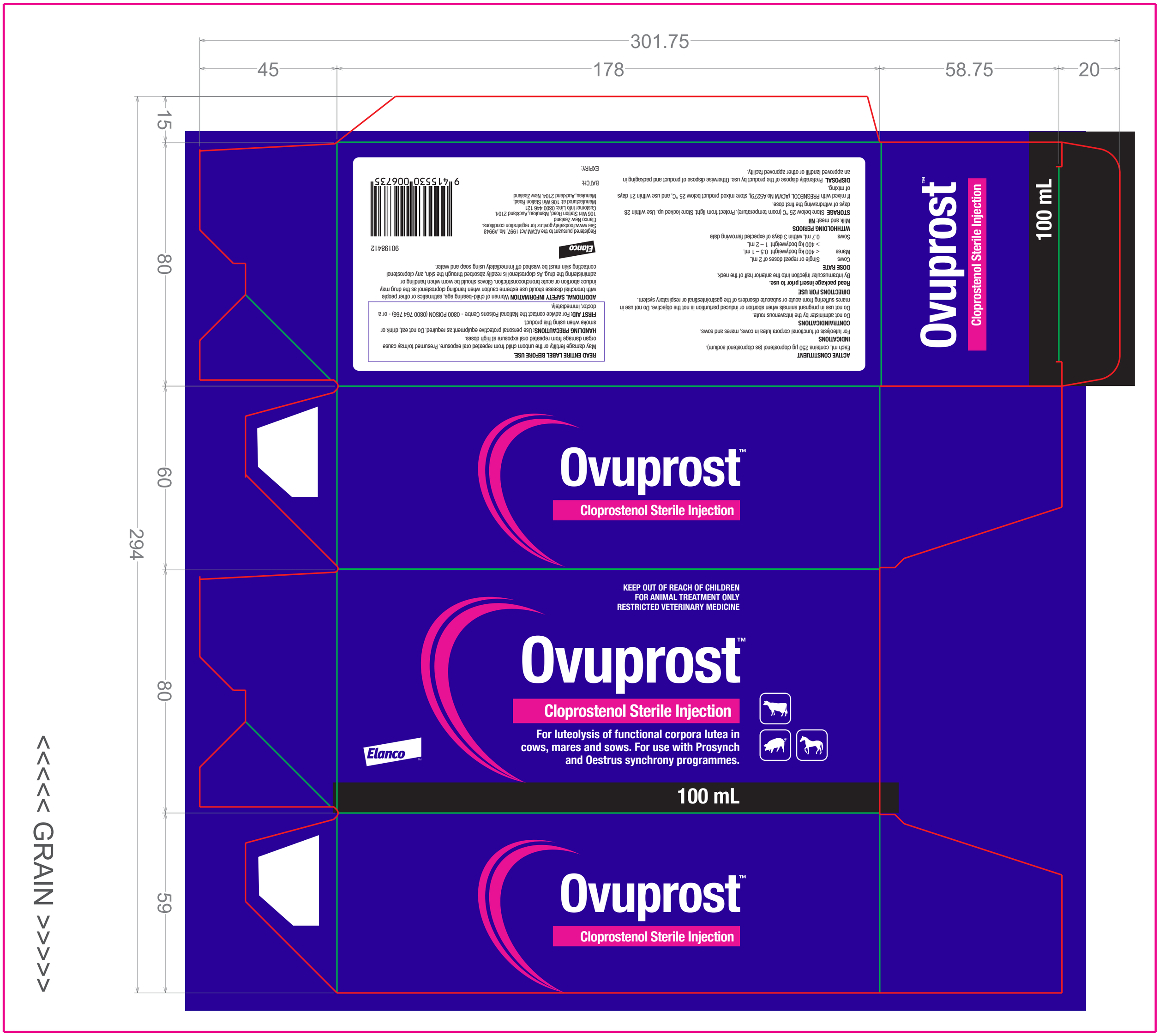
NON PRINTING	PMS VIOLET C	PMS RHODAMINE RED C	BLACK

GTIN:	GTIN Not Required	Proof #	P2a
		By/Date	EZ 14-MAR-2022
Barcodes/Type:	EAN 13: 9415530006735	Minimum Core Data Point Size:	5.5pt
Template:	178mm (W) × 60mm (D) × 80mm (H)	Packaging Spec(s):	N/A
		Add. Info:	N/A

ARTWORK INFO

BLUE #:	700751APB	Product Name:	OVUPROST
Item Code:	9019841 2	Component:	Carton
Product Code:	N/A	Pack Size:	100 ml
Previous Item Code	8630199 7		

PRODUCT INFO



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DIRECTIONS FOR USE
Do not use in pregnant animals when abortion or induced parturition is not the objective. Do not administer intravenously. Do not use in mares suffering from acute or subacute disorders of the gastrointestinal or respiratory system.

Cows: Single or repeat doses of 2 mL (500 µg Cloprostenol) by intramuscular injection in the anterior half of the neck.

Mares: Up to 400 kg bodyweight: 0.5 – 1 mL (125 – 250 µg Cloprostenol) by intramuscular injection.

Over 400 kg bodyweight: 1 – 2 mL (250 – 500 µg Cloprostenol) by intramuscular injection.

Sows: Single dose of 0.7 mL (175 µg Cloprostenol) by intramuscular injection in the anterior half of the neck within 3 days of expected farrowing date.

ADVERSE 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.

In sows, occasional side effects including increased respiration rate and biting of farrowing crate bars have been observed. Such reactions are usually transient and of little clinical significance.

WITHHOLDING PERIODS
Milk and meat: **Nil**

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READ ENTIRE LABEL BEFORE USE.

May damage fertility or the unborn child from repeated oral exposure. Presumed to/may cause organ damage from repeated oral exposure at high doses.

HANDLING PRECAUTIONS:
Use personal protective equipment as required. Do not eat, drink or smoke when using this product.

FIRST AID:
For advice contact the National Poisons Centre – 0800 POISON (0800 764 766) – or a doctor, immediately.

ADDITIONAL SAFETY INFORMATION
Women of child-bearing age, asthmatics or other people with bronchial disease should use extreme caution when handling cloprostenol as the drug may induce abortion or acute bronchoconstriction. Gloves should be worn when handling or administering the drug. As cloprostenol is readily absorbed through the skin, any cloprostenol contacting skin must be washed off immediately using soap and water.

STORAGE
Store below 25 °C (room temperature). Protect from light. Store locked up. Use within 28 days of broaching the vial when used in a sterile manner, or discard the unused portion.

DISPOSAL
Preferably dispose of the product by use. Otherwise dispose of product and packaging in an approved landfill or other approved facility.

PRESENTATION
20 mL glass/PET/HDPE vial.

Registered pursuant to the ACVM Act 1997, No. A9948.
See www.foodsafety.govt.nz for registration conditions.

ELANCO NEW ZEALAND
106 Wiri Station Road, Manukau, Auckland 2104.
Customer Info Line: 0800 446 121

Manufactured at: 106 Wiri Station Road,
Manukau, Auckland 2104.

KEEP OUT OF REACH OF CHILDREN
FOR ANIMAL TREATMENT ONLY
RESTRICTED VETERINARY MEDICINE

Elanco™

Ovuprost™

Prostaglandin (PGF2α) Injection

DESCRIPTION
A clear, sterile, aqueous solution for injection. Each mL contains 250 µg Cloprostenol (as sodium salt). Cloprostenol is a functional synthetic analogue of the naturally occurring PGF2α. In the reproductive system, prostaglandins (PGs) play a role in ovulation, luteolysis, gamete transport, uterine motility, expulsion of foetal membranes and sperm transport in both the male and female tracts. PGs are employed in reproductive therapeutics primarily for their potent luteolytic effects.

MODE OF ACTION
PGF2α causes rapid regression of functional corpora lutea, with resultant rapid decline in progesterone production. Luteolysis is usually followed by ovarian follicular development and a return to oestrus with normal ovulation.

The precise mechanism of PG-induced luteolysis is uncertain but may relate to blood flow changes in the utero-ovarian vessels, inhibition of the normal ovarian response to circulating Gonadotrophin, or stimulation of catalytic enzymes. PGF2α also has a direct stimulatory effect on uterine smooth muscle, causing contraction and a relaxant effect on the cervix.

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.

INDICATIONS
For luteolysis of functional corpora lutea in cows, mares and sows.

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.

Ovuprost can be used in the following clinical situations:

1. Synchronisation of the oestrus cycle for controlled breeding
Ovuprost alone can be used in a number of treatment regimens to synchronise the oestrus cycle of groups of cows. Some of these are described below:

Double Prostaglandin Programme – Two injections of Ovuprost 14 days apart. Artificial insemination or natural mating at the induced oestrus, which should be detected 2 – 4 days after the second injection.

Why Wait Programme – Heat detection during the first 5 – 7 days of the mating period and artificial insemination or natural joining of cows observed in oestrus. Injection of cows not observed in oestrus with Ovuprost at the end of the 5 – 7 day period and artificial or natural mating at the induced oestrus, which should be detected 2 – 4 days after injection.

Modified Why Wait Programmes – Heat detection during the 6 days prior to the start of mating. Cows not observed in oestrus are given a single injection of Ovuprost on mating start date. Cows observed in oestrus are given a single injection of Ovuprost on day 5 of the mating period. In both groups artificial or natural mating at the induced oestrus which would be detected 2 – 4 days after the injection.

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PGF2α + GnRH Programmes – Injection of Prostaglandin PGF2α (Ovuprost) in combination with Gonadotrophin Releasing Hormone (Ovurelin) followed by fixed time artificial insemination (FTAI).

One such programme may be summarised as follows:

Day 0	GnRH administration
Day 7	PGF2α administration
Day 9	GnRH administration (48 hours after PGF2α)
Day 10	Insemination 8 – 24 hours after second GnRH

Insemination is performed at a fixed time 8 – 24 hours after the second GnRH dose, regardless of the presence or absence of visible oestrus. Synchronisation of ovulation, achieved by the protocol above, has a degree of precision that allows fixed time insemination, which provides numerous management and economic benefits, particularly in situations where the level of oestrus detection is low. Large groups of cows may be inseminated together, the need for oestrus detection in the first round is eliminated, the calving to conception interval is reduced and a tighter calving pattern is achieved. This protocol has compared favourably against standard prostaglandin programmes in terms of reproductive parameters such as pregnancy rate and calving to conception interval. GnRH / PGF2α oestrus synchronisation protocols are intended for lactating dairy cattle. Variable results are reported in the literature for the application of GnRH / PGF2α in heifers.

2. Treatment of anoestrus
One such programme is Prosynch, which can be summarised as follows:

Day 0	Insertion of Progesterone (P4) device and injection of GnRH (Ovurelin).
Day 7	Removal of P4 device and injection of PGF2α (Ovuprost)

Then either:
A. With Prosynch (Hybrid) mate to detected oestrus over the next 72 hours and on Day 10 inject all remaining cows with no visible oestrus (so not mated) with GnRH (Ovurelin). Then employ Fixed Time AI within 24 hours. **Or:**

B. With Prosynch (FTAI) inject with GnRH (Ovurelin) on day 9 and Fixed Time AI between 16 – 20 hours after 2nd Ovurelin injection.

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 Ovuprost administration. Oestrus should commence 2 – 4 days following treatment, with artificial insemination or joining at the detected heat. Failure of oestrus induction 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 Ovuprost 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 Ovuprost alone after day 150 of gestation.

5. Termination of abnormal pregnancy (e.g. expulsion of mummified foetuses)
Foetal death may result in the mummification of the foetus in utero. Treatment with Ovuprost 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 (hydramniosis or hydroallantois) can be a life threatening condition, and is rarely resolved by surgical drainage. Termination of pregnancy by Ovuprost is often the preferred treatment option.

6. Induction of parturition (not for routine induction – see Code)
Parturition may be induced using Ovuprost 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 Ovuprost. All cows 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, Ovuprost 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, stimulate uterine defence mechanisms and further aid 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. 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. Ovuprost 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 Ovuprost 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% of mares, and responds to a single injection of Ovuprost.

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. Ovuprost 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 Ovuprost 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. Ovuprost 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 35 following conception. Following the formation of the endometrial cups at day 35 treatment with a single injection of PG may fail to induce abortion, and Ovuprost must be administered at daily intervals for 4 days to induce abortion in such mares. Mares in which abortion is induced after day 35 do not return to oestrus until the endometrial cups cease functioning.

7. Nomination of time of service
Ovuprost 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
Ovuprost may be employed to synchronise the cycles of a group of mares, for example donor and recipient mares used in embryo transfer Programmes.

SOWS

In pigs the corpus luteum is refractory to the effects of PGF2α in the first 11 – 12 days post ovulation. The period during which Cloprostenol can be employed for oestrus manipulation in cyclic sows is too short to be clinically useful for oestrus synchronisation.

In the sow the production of progesterone by the corpus luteum is responsible for the maintenance of gestation; parturition commences when blood PGF2α levels rise and cause luteolysis. A single injection of Cloprostenol administered to sows between days 111 – 117 of gestation will induce parturition within 48 hours. Most sows farrow within 36 hours following treatment with Ovuprost. Induced parturitions proceed normally and piglet survival is unaffected by the use of Cloprostenol, provided parturition is not induced too prematurely, i.e. more than 3 days prior to expected due date. Fertility of Cloprostenol treated sows at post-weaning oestrus is normal.