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<u>CYCLASE</u>

Introduction:

CYCLASE contains cloprostenol sodium, a synthetic analogue of prostaglandin F2 α , a potent luteolytic agent. Prostaglandins are 20 carbons atoms unsaturated fatty acids synthesized like local hormones in most of organic tissues. Prostaglandins are classified in 9 groups (A to I), subdivided in subgroups 1, 2 and 3. In domestic animals the most important prostaglandin is PGF2 α of which Cloprostenol is a synthetic functional analogue.

Action:

In the reproductive system prostaglandins suits an important role in the ovulation, luteolysis, gamete transport, uterine motility, fetal membranes and spermatozoid transport in males. Prostaglandins are widely used in reproductive therapeutic for its potent luteolytic effect. The PGF2α cause the functional and morphological regression of corpus luteum, with a quickly descent on progesterone production. Luteolysis is useful follow up for ovary follicles development and oestrus return with ovulation. In cattle the oestrus returns 2 to 4 days after luteolysis and in horses 2 to 5 days after ovulation when animals are insensitive to the luteolitic effect of prostaglandins. PGF2α has a direct stimulant effect on smooth musculature causing contraction and relaxing effects on uterus.

Formula:

Cloprostenol Sodium263 µg Excipients......e.q 1 mL

Species which the veterinary medicinal product is intended for: Bovine, Equine, Porcine, Ovine y Caprine.

Therapeutic indications:

Bovine:

- Oestrus synchronization and ovulation.
- Use in earlier postpartum to improve reproductive efficiency.
- Termination of early pregnancy.
- Removal mummified foetus.
- Parturition induction.



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- Fetal membranes retention, chronic purulent endometritis (pyometra).
- Luteal cysts.

Equine:

- Anoestrus treatment.
- Oestrus cycle handling.
- Abortion induction.

Porcine:

• Parturition induction.

Ovine & Caprine:

• Oestrus induction and synchronization.

Dosage:

Bovine: one dose of 2 mL (500 μ g of Cloprostenol) or two doses of 2 mL each one (500 μ g of Cloprostenol) separated for 11 to 14 days.

Equine: a simple dose of 1 to 2 mL (250 to 500 μ g of Cloprostenol) depending on the corporal weigh or two doses of 1 to 2 mL separated for 14 days.

Porcine: one simple dose of 0.7 mL (175 µg of Cloprostenol) within 3 days of expected parturition date, induce parturition 24 hours after treatment.

Ovine and Caprine: a single dose of 0.5 mL (125 µg of Cloprostenol) or two similar doses separated for 9 to 12 days. In Caprine, it could be combined with progestagens applying 0.5 mL 9 days after Progestagen vaginal insertion.

Route of administration: Intramuscular injection

Toxicity data:

The product has a wide safety margin. Occasional side effects have been observed following the intramuscular administration of prostaglandins. These effects have not harmful effects on animal and require no antidotes. In cattle, have reported increases in body temperature and salivary secretion,



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associated with the administration of 5-10 times the recommended dose. In equines symptoms such as sweating, increased breathing and heart rhythms, ataxia, watery diarrhea and moderate signs of abdominal pain have been observed. Such reactions have resulted from excessive doses, and are usually moderate and transitory. The use of analgesics may relieve colic if necessary.

 DL_{50} (rats) SC = >5 mg/kg DL_{50} (rats) IM = >5 mg/kg DL_{50} (rats) IV = >5 mg/kg DL_{50} (rats) Oral = >25 mg/kg DL_{50} (mouse) IM = 350 mg/kg

<u>Pharmaceutical form:</u> Injectable aqueous solution

Commercial presentations:

-Vial containing 20 ml of Cloprostenol Sodium 263 µg/ml

-Vial containing 50 ml of Cloprostenol Sodium 263 $\mu\text{g/ml}$

-Vial containing 100 ml of Cloprostenol Sodium 263 $\mu\text{g/ml}$

Withdrawal period:

MEAT: Do not use less than 1 day before slaughter for human consumption. MILK: Zero days.

Precautions:

- Store below 25°C (air conditioning), protected from light. Do not freeze.
- In transport, should be kept in a cool, dry place and protected from light.
- No special care is required in the destruction of the container.

PRODUCT USE FOR REPRODUCTION MANAGEMENT

VETERINARY USE ONLY

KEEP OUT OF REACH OF CHILDREN



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