INSTRUCTIONS
for the use of the veterinary medicinal product Estronolum
1 General Information

1.1 The veterinary drug Estronolum.

International non-proprietary name: Cloprostenol.

Pharmaceutical form: solution for intramuscular injection.

1.2 The veterinary medicinal product Estronolum (hereinafter referred to as the product) is a clear, colorless liquid without mechanical impurities.

1.3 Each 1.0 ml of the product contains 0.25 mg of cloprostenol (as cloprostenol sodium) as the active ingredient and excipients – citric acid, sodium hydroxide, distilled water.

1.4 The product is available in colorless glass vials of 10.0 and 50.0 ml.

1.5 The product must be stored in the manufacturer's packaging (List B) protected from direct sunlight at a temperature between +5 °C and +25 °C. Keep out of reach of children.

1.6 Shelf life of the product is 2 (two) years from the date of manufacture if storage conditions are observed. After opening and withdrawing the first dose, the contents of the vial may be stored at a temperature between +2 °C and +8 °C and used within 24 days. Do not use after the expiration date. Unused product must be disposed of in accordance with legislation requirements.

1.7 Dispensed without a veterinarian’s prescription.

2 Pharmacological Properties

2.1 Pharmacological group: hormones and their antagonists.

2.2 Cloprostenol, included in the composition, is a synthetic analogue of prostaglandin F2α. The mechanism of action of the product is based on the luteolytic effect (regression) of the corpus luteum in the ovaries. During the luteal phase of the estrous cycle, it causes regression of the corpus luteum, removes the inhibitory effect of progesterone on the hypothalamic-pituitary complex, which promotes follicular growth in the ovaries and, in turn, increases estrogen levels in the blood, resulting in estrus and heat in female animals. The product enhances uterine contractile function and shows biological activity only in the presence of actively functioning corpora lutea in the ovaries.

2.3 After intramuscular administration, the product is rapidly absorbed, reaching maximum concentrations in approximately 15–90 minutes. In animals, cloprostenol is extensively metabolized to form cloprostenol tetranor acid, and is excreted as β-lactone and glucuronic acid conjugates. Cloprostenol is excreted mainly in the urine, with an average half-life of 75–80 minutes to 3 hours.

2.4 From the moment of administration to the first signs of estrus, 46–70 hours pass. The optimal time for artificial insemination after administration is 76 hours.

2.5 The product is classified as moderately hazardous (Hazard Class III according to GOST 12.007.01-76).

3 Directions for Use

3.1 The product is administered intramuscularly for estrus synchronization; treatment of cows with luteal and follicular cysts, persistent corpora lutea, uterine subinvolution and endometritis; treatment and prevention of functional ovarian disorders in pigs, induction and synchronization of farrowing; termination of pregnancy in animals (as indicated).

3.2 For estrus synchronization in cows and heifers, the product is administered twice at a dose of 2 ml with a 10-day interval. The first dose is administered during any phase of the estrous cycle (in cows from day 40 to 60 after calving). If no signs of estrus are observed on day 11 after the first dose, a second dose should be administered, and on day 14 (72–76 hours after the second dose), fixed-time artificial insemination is carried out (regardless of external signs of estrus) with repeated insemination on day 15.

3.3 To treat cows with luteal ovarian cysts, administer a single dose of 4.0 ml. For enhanced therapeutic effect, administer the same dose along with a subcutaneous injection of a gonadotropin-containing product at a dose of 2.5–3.0 thousand IU.

3.4 In cows with follicular ovarian cysts, administer a single subcutaneous injection of a gonadotropin-containing product at a dose of 4–5 thousand IU or 5.0 ml of surfagon intramuscularly for three days. After 10–12 days, if the animal has not come into estrus, inject 2.0 ml of the product.

3.5 In cows with persistent corpora lutea, administer 2.0 ml of the product, and perform artificial insemination at the first signs of estrus. If estrus does not occur, repeat the 2.0 ml injection on the 11th day after the first injection, with insemination 72–76 hours later, according to clause 3.2 of this instruction.

3.6 To treat cows with postpartum endometritis and uterine subinvolution, administer 2.0 ml twice at 10–11 day intervals, along with etiological, pathogenetic and symptomatic treatment.

3.7 To treat sows with functional ovarian disorders and restore reproductive function in animals not showing estrus within 12 days after weaning, administer 1.0 ml in combination with a gonadotropin-containing product at a dose of 10 IU per 1 kg of body weight.

3.8 For synchronization of farrowing in sows and prevention of postpartum diseases, administer the product on day 113–114 of pregnancy at a dose of 0.7 ml per animal. Farrowing usually occurs within 24–35 hours.

3.9 Unwanted pregnancy in cows (as indicated) is terminated by administering 2.0 ml of the product.

3.10 No side effects or complications are observed when the product is used in recommended doses.

3.11 The product is contraindicated in pregnant animals as it induces abortion.

3.12 Slaughter of animals for meat is prohibited within 24 hours after administration. Meat from animals slaughtered before this period may be used for feeding carnivorous animals. Milk from cows may be used for human consumption without restrictions.

4 Precautionary Measures

4.1 When handling the product, observe personal hygiene and safety precautions.

4.2 Persons under 18 years of age, pregnant women, and nursing mothers should not handle the product.

5 Claims Procedure

5.1 In the event of complications following use of the product, its use must be discontinued and the consumer should contact the state veterinary institution in their region. Veterinary professionals will examine compliance with all instructions for use. If adverse effects of the product on the animal are confirmed, samples will be taken in sufficient quantity for laboratory testing (at least 3 packages from the batch in question), and an official sampling report will be drawn up and sent to the State Institution "Belarusian State Veterinary Center" to confirm compliance with regulatory documentation. Address: Minsk, Krasnaya St., 19a, Tel.: 290-42-75.

6 Manufacturer Information

6.1 Manufacturer: Production Cooperative "Biogel".

Legal address: Republic of Belarus, 220035, Minsk, 65 Timiryazeva St., office 313.

Production site address: Republic of Belarus, 222685, Minsk Region, Stolbtsovsky District, village of Nivnoye.

Manufactured by order of the Private Enterprise "Letyal", Republic of Belarus, 220075, Minsk, 1E Inzhenernaya St.

The instructions for use of the product were developed by employees of the RUE "Scientific Research Institute BioPharm" (A.E. Vysotsky, A.P. Lysenko) and Private Enterprise "Letyal" (A.N. Bezborodkin).