

**Summary of Veterinary Product Characteristics  
CLOPROSTENOL-TRV**

**1. GENERAL PRODUCT INFORMATION**

1.1 Cloprostenol-TRV.

International non-proprietary name: cloprostenol

1.2 Dosage form is solution for injection.

1 cm<sup>3</sup> contains 0.25 mg of sodium cloprostenol, excipients (benzyl alcohol) and water for injection.

1.3 Appearance, the veterinary product is a clear liquid from white to yellow, without impurities

1.4 The product is packed in glass or polymer vials of 10, 20, 30, 50, 100, 200 and 400 ml, hermetically closed with rubber stoppers and tamper resistant aluminum caps. Capping with other stoppers is allowed, ensuring the container closure integrity.

1.4 Cloprostenol-TRV is stored under the requirement of the list B: in a dry, dark place at temperatures from plus 5°C to plus 25°C. Shelf life is two years from the date of manufacture, subject to storage conditions. The shelf life once opened is three days at a temperature of plus 5°C to plus 25°C.

**2. PHARMACOLOGICAL PROPERTIES**

2.1 Cloprostenol-TRV belongs to the pharmacological group: hormones and their antagonists.

2.2 Cloprostenol is a synthetic analogue of prostaglandin F2a. It has a luteolytic effect, causes functional and morphological regression of the corpus luteum, promotes the growth of follicles in the ovaries, an increase in the level of estrogen in the blood, the manifestation of estrus, sexual heat and subsequent ovulation of mature follicles. The period from veterinary product administration to the first signs of estrus is 48-72 hours.

2.3 Cloprostenol causes contraction of the smooth muscles of the uterus, respiratory tract, gastrointestinal tract and blood vessels.

2.4 In the body of animals, cloprostenol is rapidly metabolized, the level of cloprostenol in the blood plasma of animals is observed for 15 minutes to 2 hours. It is excreted mainly in the urine. Half-life is 5-8 hours

2.5 Cloprostenol-TRV, according to the degree of the exposure, belongs to low-hazard substances (hazard class 4 according to GOST 12.1.007-76).

**3. DOSAGE AND INDICATION**

3.1 Cloprostenol-TRV used in cows, calves and sows for the regulation of reproductive function and treatment for gynecological and obstetric pathology, including synchronization of the sexual cycle in cows and calves, induction of farrowing in sows; treatment of cows with functional disorders of the ovaries (persistent corpus luteum, luteal and follicular cysts, quiet hunting, violation of the rhythm of the sexual cycle), prevention and treatment of subinvolution of the uterus and endometritis, termination of pregnancy in fetal pathology.

3.2 The product is administered intramuscularly or subcutaneously in the following doses:

- cows with persistent corpus luteum - at a dose of 2 ml, artificial insemination at the first signs of the heat, if heat has not begun - the veterinary product is injected again at a dose of 2 ml on the 11th day after the first injection, followed by insemination 72-76 hours later;

- in the treatment of cows with luteal ovarian cysts - once in a dose of 4 ml, at the same time injecting FFA subcutaneously in a dose of 2.5-3.0 thousand mouse units;

- for follicular ovarian cysts in cows - once subcutaneously chorionic gonadotropin at a dose of 4-5 thousand units or intramuscularly surfagon 50 mcg for 3 days, after 10-12 days, animals that have not come into the heat are injected with the veterinary product at a dose of 2 ml intramuscularly;

- heat synchronization in cows and calves - the veterinary product is administered twice at a dose of 2 ml per animal with an interval of 10 days. The first dose of the veterinary product is administered at

any phase of the sexual cycle (in cows from 40 to 60 days after birth). In the absence of arousal stage on the 11th day after the first injection, a second dose should be administered, and on the 14th day (72-76 hours after the second injection), frontal artificial insemination (regardless of external signs of the heat) is performed with repeated insemination on the 15<sup>th</sup> day;

- for the treatment of cows with postpartum endometritis and subinvolution of the uterus - twice every 10-11 days at a dose of 2 ml with the simultaneous appointment of etiotropic, pathogenetic and symptomatic therapy;

- to synchronize farrowing in sows and prevent postpartum diseases - injected in a dose of 0.7 ml on 113-114 days of gestation;

- to restore reproductive function in sows that did not show heat within 12 days after weaning piglets - injected in a dose of 1 ml in combination with one of the gonadotropic veterinary products;

- to terminate an unwanted pregnancy - the veterinary product is administered in a dose of 2 ml.

3.3 In the recommended doses, the veterinary product does not have a toxic effect on the body of animals and does not cause adverse effects.

3.4 In case of an overdose of the veterinary product in animals, there may be an increase in pulse and respiration, bronchial spasms, an increase in body temperature, increased bowel movements and urination, salivation and vomiting.

3.5 The use of the veterinary product is contraindicated in case of hypersensitivity to the components of the veterinary product. It must not be used in pregnant animals (except in cases of termination of pregnancy).

3.6 Livestock products during the period of administration of the veterinary product are used without restrictions.

#### **4. PREVENTIVE MEASURES**

4.1 Generally accepted personal hygiene measures and safety rules should be observed when working with this veterinary product.

#### **5 CLAIMING PROCEDURE**

5.1 In case of complications after the use of the veterinary product, its use is discontinued and the consumer should apply to the State Veterinary Institution on the territory of its location. Veterinary specialists of this institution study compliance with all the rules for the use of the veterinary product in accordance with the instructions. After the confirmation of a veterinary product adverse effect to the animal, the veterinary specialists take samples in the required amount for laboratory tests, at least three unopened vials of the veterinary product from the batches that caused the complication, a sampling report is drawn up and sent to the State Institution "Belarusian State Veterinary Center" (220005, Minsk, Krasnaya Str. 19-a, tel. 290-42-75) for confirmation of compliance with regulatory documents.

#### **6 FULL NAME OF MANUFACTURER**

6.1 Stovek, LLC, Republic of Belarus, 222660, Minsk Region, Stolbtsy, Zadvoryenskaya St., 2

The Summary of Veterinary Product Characteristics was developed by the employees of Stovek, LLC (T.A. Soboleva, V.V. Sobolev).

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Department of Veterinary and Food Control of the Ministry of Agriculture and Food of the Republic of Belarus Veterinary Medicinal Product Council Approved Chairman [Signature] Secretary [Signature] Expert [Signature] 23.12.2020 Minutes No. 112
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