APPROVED
Veterinary Medicinal Product Council
Minutes No. 102 dated June 19, 2019

**Summary of Veterinary Product Characteristics**
**IVERMECTIN 1%-TRV**

## 1. GENERAL PRODUCT INFORMATION

1.1 Ivermectin 1%-TRV.

1.2 Ivermectin 1%-TRV is an antiparasitic veterinary product, solution for injection, clear liquid from colorless to light yellow, without impurities.

1 $cm^3$ of the veterinary product contains 10 mg of ivermectin, excipients (propylene glycol, benzyl alcohol, 1-methyl 2-pyrrolidone) and water for injection.

1.3 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 Ivermectin 1%-TRV is stored under requirements of list B in a dry, dark place at temperatures from plus 5°C to plus 25°C. Shelf life is three years from the date of manufacture, subject to storage conditions. The shelf life once opened is 21 days at a temperature of plus 5°C to plus 25°C.

## 2. PHARMACOLOGICAL PROPERTIES

2.1 Ivermectin is a macrocyclic lactone with a broad spectrum of antiparasitic action on the imaginal and larval phases of development of nematodes in the gastrointestinal tract and lungs, as well as ticks, insects and gadfly larvae parasitizing farm animals.

2.2 The mechanism of action of the veterinary product on the parasite organism is that ivermectin stimulates the release of the inhibitory neurotransmitter gamma-aminobutyric acid (GABA) in presynaptic neurons, causing the transmittance of signals from the nerve cell to the muscle tissue cell, it blocks the transmission of nerve impulses, causing the paralysis and death of the parasite.

There is no cross-resistance to other antiparasitic veterinary products (benzimedazole, cholinesterase inhibitors).

2.3 The veterinary product is rapidly absorbed from the injection site and penetrates into the organs and tissues of the animal, providing a long-term antiparasitic effect. The therapeutic concentration is maintained for 10-12 days after administration.

2.4 Ivermectin is partially metabolized in the liver, excreted from the body mainly with bile and urine, in lactating animals - with milk. Ivermectin is rapidly destroyed in the external environment.

2.5 Ivermectin 1%-TRV, according to the degree of exposure, is classified as a low-hazard substance (hazard class 4 according to GOST 12.01.007-76).

## 3. DOSAGE AND INDICATION

3.1 The product is used for therapeutic and prophylactic purposes in cattle and small ruminants with dictyocaulosis, haemonchosis, thelaziosis, strongyloidosis, esophagostomosis, bunostomosis, habertiosis, trichocephalosis, sifunculatosis, hypodermosis, psarcosis, psarcosis. In pigs with ascariasis, esophagostomosis, strongyloidosis, trichocephalosis, metastrongylosis, stefanurosis, hematopinosis and sarcoptic mange.

3.2 The veterinary product is administered intramuscularly or subcutaneously once in the following doses, in accordance with the table.

Table – Doses

| **Animal species** | **Recommended dose** |
|---|---|
| cattle | subcutaneously, in the area of the arm at a dose of 1 ml per 50 kg (0.2 mg of active substance per 1 kg) of the animal weight |
| sheep, goats | subcutaneously, in the back third of the neck at a dose of 1 ml per 50 kg (0.2 mg of active substance per 1 kg) of the animal weight |
| pigs | intramuscularly, in the area of the ear base at a dose of 1 ml per 33 kg (0.3 mg of active substance per 1 kg) of the animal weight |

In case of severe damage to animals with sarcoptoidosis, the treatment is carried out twice with an interval of 8-10 days.

In view of the possible painful reaction, the maximum volume for injection in one place should not exceed 10 ml.

3.3 Treatment of animals with nematodes is carried out in the fall before stalling and in the spring before pasture, against gadfly infestations - immediately after the end of the summer of gadflies, with sarcoptoidosis and entomoses - according to indications.

3.4 In recommended doses, Ivermectin 1%-TRV has no toxic effect on the body and does not cause adverse effects. Before mass deworming, each batch of the veterinary product is preliminarily tested on a small group (5-10 heads) of animals. In the absence of complications within 2-3 days, all livestock are treated.

3.5 With increased individual sensitivity to the veterinary product, some animals may experience agitation, increased salivation, vomiting, increased frequency of defecation and urination, ataxia. These symptoms resolve on their own, without the use of therapeutic agents. A swelling may appear at the injection site, which resolves after 3-5 days.

3.6 The veterinary product must not be used for productive animals, whose milk is used for human consumption, weakened and emaciated animals, as well as for pregnant animals at least two weeks before calving.

3.7 Slaughter of animals for meat is allowed no earlier than 21 days, pork meat - 28 days after the last administration of the veterinary product.

## 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, (A.Yu. Finogenov, T.A. Soboleva, E.G. Finogenova).

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19.06.2019 Minutes No. 102