APPROVED
Veterinary Medicinal Product Council
Minutes No. 104 dated October 25, 2019

Summary of Veterinary Product Characteristics
AMPROLIUM 100-TRV

1. GENERAL PRODUCT INFORMATION

1.1 Amprolium 100-TRV.

1.2 Amprolium 100-TRV is an anticoccidial product for oral administration, white to light yellow powder without impurities, 1 g contains 900 mg of amprolium hydrochloride as an active ingredient and excipients (dextrose).

1.3 The product is packed in foil bags of 100, 500, 1000, 5000 and 10000 g and in multilayer paper bags with a polyethylene insert of 10, 20, 25, 30 kg. Polyethylene bags liners must be packed hermetically.

1.4 Amprolium 100-TRV is stored in a dry, dark place at a temperature from 0 ° C to plus 25 ° C. Shelf life - three years from the date of manufacture, subject to storage conditions.

2. PHARMACOLOGICAL PROPERTIES

2.1 Amprolium 100-TRV is a broad spectrum anti-eimeriosis veterinary product. Amprolium hydrochloride is a pyrimidine derivative, is active against the Eimerian genus of other Eimeria species parasitizing in poultry, and is compatible with vitamins and feed additives used in poultry farming.

2.2 Amprolium hydrochloride inhibits the development of eimeria at the stage of merogony of the first and second generation, the mechanism of action of which is due to the proximity of its chemical structure to thiamine (Vitamin B1), which is necessary for the vital activity of coccidia. Due to active transport, amprolium penetrates the parasite cell better than thiamine and occupies the active binding sites of the vitamin, which leads to disruption of carbohydrate metabolism and the death of the parasite.

2.3 Amprolium hydrochloride does not penetrate the cell membranes of the intestinal mucosa of poultry and mammals, and has low toxicity for warm-blooded animals.

2.4 Amprolium is practically not absorbed in the gastrointestinal tract, exhibiting anti-eimeriosis effect on mucous and submucous membranes. It is excreted mainly unchanged: with feces within 3-4 days and does not interfere with the formation of immunity to eimeriosis.

2.5 Amprolium 100-TRV, according to the degree of exposure, is classified as a low-hazard substance (hazard class 4 according to GOST 12.01.007).

3. DOSAGE AND INDICATION

3.1 Amprolium 100-TRV is used as a therapeutic and prophylactic agent for eimeriosis in broiler chickens, replacement poultry, breeding poultry, as well as cattle and small cattle.

3.2 The veterinary product is administered orally to poultry, large and small cattle in groups with feed or water:

- for prophylactic purposes 130-150 g per ton of drinking water or feed (120 mg of active substance per 1 liter of water or 1 kg of feed);
- for therapeutic purposes, 250-300 g per ton of drinking water or feed (240 mg of active substance per 1 liter of water or 1 kg of feed) for 5-10 days in a row, followed by a transition to a prophylactic dose

3.3 For broilers, for prophylactic purposes, the veterinary product is used from 3-5 days of age.

Replacement youngsters are prescribed from 1 day of life and canceled 3 weeks after transfer for keeping in a cage.

Layers with floor maintenance - are prescribed from 1 day of life to 5 weeks of age in a prophylactic dose.

Turkeys - from 1 day of age to 10 weeks of age.

For prophylactic purposes, the veterinary product is administered to calves within 21 days, to sheep - within 5 days.

3.4 During the period of treatment, the poultry should not have access to other water sources than the medicated water. Medicated drinking water should be refreshed or replaced every 24 hours.

3.5 To ensure an even distribution of the veterinary product, the daily dose is mixed with a small amount of feed, and then, with thorough mixing, is added to the remaining feed, calculated for consumption during the day.

3.6 The effectiveness of amprolium does not decrease when antibiotics, minerals, vitamins, including thiamine, are included in the feed at a dose of 0.2-0.4 mg per 1 kg of feed. The counteracting effect of thiamine is fully manifested only when the ratio with amprolium is 1: 2.

3.7 Adverse effects, except for cases of individual hypersensitivity to the components of the medicinal product, were not identified. If symptoms of an allergic reaction appear, the veterinary product is discontinued and, if necessary, symptomatic therapy is started.

3.8 Contraindications. The use of the veterinary product is contraindicated in conjunction with other eimerostatics. Must not be used for replacement young poultry after 16 weeks of age and poultry whose eggs are used for human consumption due to the accumulation of amprolium in eggs.

3.9 Slaughter of poultry for meat is allowed no earlier than 5 days after the last use of the veterinary product.

The meat of animals and poultry, forcedly killed before the expiration of the specified period, can be used to feed carnivores.

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

6.2 The Summary of Veterinary Product Characteristics was developed by the employees of Stovek, LLC: Ph.D. in veterinary science, associate professor A.Yu. Finogenov, T.A. Soboleva, Ph.D. in veterinary science E.G. Finogenova.

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Veterinary Medicinal Product Council
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