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

Summary of Veterinary Product Characteristics
SALINOMYCIN 12-TRV

1. GENERAL PRODUCT INFORMATION

1.1 Salinomycin 12-TRV.

1.2 Salinomycin 12-TRV is an anticoccidial preparation for oral administration, powder from light gray to gray-brown, with a specific odor, without impurities, each g contains 120 mg of sodium salinomycin as an active ingredient and excipients (sucrose)..

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 Salinomycin 12-TRV is stored in a dry, dark place at a temperature from 0 ° C to plus 25 ° C. The shelf life in the manufacturer's packaging, subject to the shelf life of three years from the date of manufacture, the shelf life of once opened product is not more than 3 months.

2. PHARMACOLOGICAL PROPERTIES

2.1 Salinomycin 12-TRV is an anti-eimeriosis agent of a broad spectrum of action of the ionophore antibiotic group. It has a coccidiostatic effect in the early stages of development of coccidia, reducing the pathological effects of parasites on animals and poultry.

2.2 The veterinary product does not cause cross-resistance with monovalent glycoside and bivalent ionophores, reliably protects against the main types of eimeria, and also increases body weight gain and feed digestibility.

2.3 Salinomycin sodium is an eimeriostatic of the ionophore group, it is active against most species of eimeria at the stage of sporozoites, trophozoites and schizonts of the first generation. Trichomonas and Cryptosporidia are not sensitive to salinomycin.

2.4 The veterinary product damages the transport of sodium and potassium in the oocyst and leads to the death of coccidia at the stage of schizogony.

2.5 The mechanism of action of the veterinary product on eimeria is based on the ability of sodium salinomycin to give complex compounds with alkali metal ions. Salinomycin sodium acts as ion carriers and the resulting violation of the intracellular ionic concentration of the parasite leads to its death.

2.6 When administered orally, sodium salinomycin is practically not absorbed from the gastrointestinal tract and exerts its effect on the mucous and submucous membranes. It is eliminated mainly unchanged with feces within 3-4 days, in laying birds - with an egg.

2.7 Salinomycin 12-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 Salinomycin 12-TRV is used as a therapeutic and prophylactic agent for eimeriosis in broiler chickens and replacement chickens; young cattle and sheep (calves and lambs with developed proventricles); pigs, caused by various types of eimeria.

3.2 The veterinary product is administered to poultry and animals orally in a group way mixed with feed in the following doses, in accordance with the table.

Table - Doses of the veterinary product

Animal species	**Recommended Dose**
broiler chickens	500 g per 1 ton of feed (60 mg of active substance per 1 kg of feed) - from the first day of life, throughout the entire growing period, excluding from the diet 5 days before the slaughter

replacement young animals	500 g per 1 ton of feed (60 mg of active substance per 1 kg of feed) - from the first day of life to 16 weeks of age
Pigs up to 4 months of age	250-450 g of the veterinary product per 1 ton of feed
Pigs 4- 6 months of age	250 g per 1 ton of feed
Calves, lambs	100 - 250 g per 1 ton of feed

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

3.4 The veterinary product can be used with vitamins, antibiotics and known feed supplements.

3.5 If the next dose of the veterinary product is missed, its administration should be resumed in the same dosage and according to the same scheme.

3.6 Adverse effects, with the exception of cases of individual hypersensitivity to the components of the medicinal product, have not been identified. Overdose in poultry and animals may experience decreased appetite, decreased water intake and weight loss.

3.7 Contraindications. The administration of the veterinary product is contraindicated simultaneously with other anti-eimeriosis agents, together with tiamulin, as well as 7 days before the start and 7 days after the end of its administration. The veterinary product is contraindicated in poultry, the egg of which is for human consumption and breeding poultry, as well as in calves and lambs with undeveloped proventricles (up to 2-3 months of age).

3.8 Slaughter of animals and poultry for meat is allowed no earlier than 5 days after the last administration 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

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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