

**Summary of Veterinary Product Characteristics
COLI 12-TRV**

1. GENERAL PRODUCT INFORMATION

1.1 Coli 12-TRV.

International non-proprietary name: colistin

1.2 Coli 12-TPV is an antimicrobial veterinary product, oral powder from white to light yellow without impurities.

1.3 1 g of the product contains 12,000,000 IU of colistin sulfate and excipients (ascorbic acid, citric acid, sucrose).

1.4 The veterinary 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 liner bags must be hermetically sealed.

1.5 Coli 12-TRV is stored under the requirement of the list B: in a dry, dark place at temperatures from 0°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 35 days.

2. PHARMACOLOGICAL PROPERTIES

2.1 Colistin (as sulfate) is an antibiotic of the polymyxin group, which are synthesized by the aerobic spore-forming bacillus *Bacillus polymyxa*. It is active against a number of gram-negative microorganisms, including: *Escherichia coli*, *Pseudomonas aeruginosa*, *Haemophilus spp.*, *Klebsiella spp.*, *Proteus spp.*, *Salmonella spp.*, *Pasteurella spp.*

2.2 The mechanism of bactericidal action of colistin sulfate lies in its combination with bacterial lipoproteins and violation of the cell wall permeability, which leads to the loss of amino acids, inorganic ions, purine and pyrimidine bases by the bacterial cell and causes its death.

2.3 When administered orally, the veterinary product is practically not absorbed from the gastrointestinal tract and has an antimicrobial effect directly in the intestine.

2.4 Colistin sulfate is excreted from the body unchanged, mainly with feces and urine.

2.5 Coli 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 Coli 12-TPV is used to treat pigs, calves, sheep and poultry with colibacteriosis, salmonellosis and other infectious diseases of the gastrointestinal tract of bacterial etiology, the pathogens of which are sensitive to colistin.

3.2 The veterinary product is administered orally to animals and poultry in a group or individual way in a mixture with feed or drinking water, for 3-5 days, in doses indicated in the table:

Table - Doses of the veterinary product

Animal species	Recommended dose	
	with water	with feed
Calves, sheep	-----	5-8 mg per 1 kg of body weight
Pigs	5-8 mg per 1 kg of body weight	5-8 mg per 1 kg of body weight
Poultry	50-75 g of the veterinary product per 1000 liters of water	-----

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

3.4 In recommended doses, Coli 12-TPV does not cause adverse effects. With frequent use or overdose, diarrhea, anorexia and allergic reactions may occur. If allergic reactions develop, the veterinary product is discontinued and antihistamines and calcium preparations are administered.

3.5 The veterinary product is contraindicated in cattle and small cattle with developed cicatricial digestion; animals and poultry with kidney and liver diseases, as well as with increased sensitivity to colistin.

The simultaneous use of the veterinary product with muscle relaxants and bacteriostatic antibiotics (macrolides, tetracyclines) is contraindicated.

3.6 Eggs of laying hens during the period of administration of the veterinary product are allowed to be used for food purposes without restrictions.

3.7 Slaughter of poultry for meat after administration of the veterinary product is allowed without restrictions. Slaughter of calves, pigs and sheep for meat is allowed 7 days after the veterinary product was administered.

The meat of animals, forcibly killed during the period of application and the next 7 days after the administration of the veterinary product, 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 (A.Yu. Finogenov, T.A. Soboleva, E.G. Finogenova).

[Stamp]:

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] 10.09.2020 Minutes No. 110	
--	--