

Summary of Veterinary Product Characteristics
COLISTIN AQUA**1. GENERAL PRODUCT INFORMATION**

1.1 Colistin aqua.

International non-proprietary name active pharmaceutical ingredient: colistin.

Dosage form: oral solution.

1.2 In appearance, the veterinary product is a clear liquid from light yellow to brown.

1.3 1 ml contains active ingredient colistin sulfate – 4 000 000 IU, excipients - propylene glycol, citric acid, lactic acid, highly purified water.

1.4 The veterinary product is packed in polymer containers (polyethylene, polymer bottles or polyethylene canisters of appropriate capacity with screw tamper resistant caps) of 100, 500, 1000, 2000, 3000, 5000 and 10000 ml.

1.5 Colistin aqua is stored under the requirement of the list B: in a 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 and transportation conditions. The shelf life once opened is 15 days subject to specified storage conditions.

After the expiration of the storage period, the unused veterinary product is disposed of in accordance with the requirements of the legislation.

2. PHARMACOLOGICAL PROPERTIES

2.1 Colistin is a peptide antibiotic of the polymyxin group, the antibacterial activity of which extends mainly to gram-negative microflora. It is synthesized by the aerobic spore-forming bacillus *Bacillus polymyxa* and has a pronounced bactericidal effect against most aerobic gram-negative microorganisms, including *Escherichia coli*, *Salmonella spp.*, *Pasteurella spp.*, *Bordetella spp.*, *Klebsiella spp.*, *Pseudomonas aeruginosa*.

2.2 The mechanism of bactericidal action of colistin is to disrupt the permeability of the cytoplasmic membrane, which leads to its destruction and subsequent lysis of the bacterial cell. Bacterial resistance to colistin develops very slowly.

2.3 With oral administration of the veterinary product, colistin sulfate is practically not absorbed in the gastrointestinal tract, is not affected by digestive enzymes and does not accumulate in tissues, which creates conditions for obtaining a high antibacterial concentration of colistin in the intestinal lumen and allows you to obtain excellent results in the treatment of intestinal diseases caused by gram-negative bacteria.

2.4 Colistin is excreted mainly in feces, mainly in an unchanged form.

3. DOSAGE AND INDICATION

3.1 The veterinary product is used to treat pigs, calves and poultry with colibacillosis, salmonella, pasteurellosis and other bacterial diseases of the gastrointestinal tract, the causative agents of which are sensitive to colistin.

3.2 The veterinary product is administered orally with drinking water individually or in groups for 3-5 days in doses according to the table:

Table - Doses of the veterinary product

Animal species	Recommended dose	
	individually	in groups
Poultry	0.2 ml of the veterinary product per 10 kg of body weight or 0.02 ml per 1 kg of body weight	100-125 ml of the veterinary product per 1000 L of drinking water
Pigs	0.25-0.5 ml of the veterinary product per 10 kg of body weight per day (diluted with drinking water in a ratio of 1:10)	0.25-0.5 L of the veterinary product per 1 ton of water
calves	0.1-0.25 ml of the veterinary product per 10 kg of animal body weight or 0.01-0.025 ml of the veterinary product per 1 kg of animal	-----

	body weight (diluted with drinking water in a ratio of 1:10)	
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3.3 During the treatment period, pigs and poultry (with a group method of administration) should receive water containing only the veterinary product. The prepared solution should be the only source of drinking water. The solution is prepared daily. If necessary, the course of treatment is repeated after 5 days.

3.4 Adverse effects, with the exception of cases of individual hypersensitivity to the components of the veterinary product, have not been identified. If symptoms of an allergic reaction appear in animals, the veterinary product is discontinued and, if necessary, symptomatic therapy is prescribed. With prolonged use of the veterinary product, dysbacteriosis may develop.

3.5 Contraindications. The use of the veterinary product is contraindicated in case of hypersensitivity to colistin sulfate, with severe renal and hepatic insufficiency. It must not be used the veterinary product in adult cattle with developed cicatricial digestion.

3.6 The veterinary product should not be used simultaneously with ampicillin for oral administration, cephalosporins for oral administration, aminoglycoside antibiotics for oral administration.

3.7 Slaughter of poultry for meat after the administration of the veterinary product is allowed without restrictions.

Slaughter of calves and pigs for meat is allowed 7 days after the veterinary product was administered.

The meat of animals, forcedly 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, Limited Liability Company, Republic of Belarus, 222660, Minsk Region, Stolbtsy, Zadvoryenskaya St., 2 for Trionis Vet, LLC, 141092, Russia, Moscow Region, Korolev, md. Yubileiny, Lesnaya St., 14, office 5

The Summary of Veterinary Product Characteristics was developed by the employees of Trionis Vet, LLC (A.Yu. Finogenov, T.A. Soboleva, E.G. Finogenova).

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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]
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