

Summary of Veterinary Product Characteristics
TYLOSIN AQUA

1. GENERAL PRODUCT INFORMATION

- 1.1 Tylosin aqua.
- 1.2 Tylosin aqua is an antibacterial veterinary product, clear solution from light yellow to yellow, 1 ml contains 200 mg of tylosin as an active ingredient and excipients - propylene glycol, lactulose, benzyl alcohol, highly purified water.
- 1.3 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.
- 1.4 Tylosin 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 conditions. The shelf life once opened is 28 days.

2. PHARMACOLOGICAL PROPERTIES

- 2.1 Tylosin is an antibiotic of the macrolide group. It is active against most gram-positive and some gram-negative microorganisms, including *Staphylococcus spp.*, *Streptococcus spp.*, *Escherichia coli*, *Pasteurella spp.*, *Haemophilus spp.*, *Leptospira spp.*, *Erysipelothrix rhusiopathiae*, *Corynebacteriu, spp.*, *Chlamydia spp.*, *Treponema spp.*
- 2.2 The mechanism of action of tylosin is based on the suppression of bacterial protein synthesis by binding of the active substance to the 50S ribosomal subunit.
- 2.3 When administered orally, tylosin is well absorbed from the gastrointestinal tract and creates therapeutic concentrations of tylosin in the blood and tissues of the animal's body.
- 2.4 The veterinary product is excreted from the body mainly in the bile and in smaller quantities in the urine.
- 2.5 The veterinary product, according to the degree of exposure belongs to low-hazard substances (hazard class 4 according to GOST 12.1.007-76).

3. DOSAGE AND INDICATION

- 3.1 Tylosin aqua is used as a therapeutic agent:
pigs - with gastroenterocolitis of bacterial etiology, dysentery, enzootic pneumonia, atrophic rhinitis, pig erysipelas, arthritis;
agricultural poultry (broilers, replacements, breeding poultry) - for respiratory mycoplasmosis, infectious sinusitis, colibacillosis, pasteurellosis and other diseases, pathogens of which are sensitive to tylosin
- 3.2 The veterinary product is administered orally with drinking water individually or in groups in doses according to the table:

Table - Doses of the veterinary product

Animal species	Recommended dose	
	individually	in groups
poultry	2-3 ml per 1 liter of water for 3-5 days (400-600 mg of active substance per 1 liter of water)	2-3 liters of the veterinary product (400-600 g of active substance) per 1 ton of water for 3 - 5 days
pigs	1.15 ml per 1 liter of drinking water (25 mg of active substance per 1 kg of animal weight) for 3-7 days	1.15 liters of the veterinary product per 1 ton of water for 3-7 days

3.3 During the period of treatment, pigs and poultry (group use to be treated) 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 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 tylosin, with severe renal and hepatic insufficiency. It must not be used in poultry, whose eggs are used for human consumption.

3.6 The veterinary product should not be used simultaneously with penicillins, cephalosporins and lincosamides.

3.7 Slaughtering of animals and poultry for human consumption is allowed no earlier than 8 days after the last use of the veterinary product.

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, 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 Stovek, 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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