

Summary of Veterinary Product Characteristics

DOXYTIL

1. GENERAL PRODUCT INFORMATION

1.1 Doxytil

1.2 Doxytil is a combined antimicrobial veterinary product, white to yellow powder for oral solution, each g contains 100 mg of doxycycline and 100 mg of tylosin as active substances and excipients - sodium citrate, citric acid, dextrose.

1.3 The veterinary product is packed in consumer packaging: foil bags of 100, 500, 1000, 5000 and 10000 g.

1.5 Doxytil is stored according to list B in a dry, dark place at a temperature from 0 ° C to 25 ° C. Shelf life - three years from the date of manufacture, subject to storage conditions.

2. PHARMACOLOGICAL PROPERTIES

1.1 Doxycycline is a semisynthetic tetracycline derivative (oxytetracycline derivative). Active against gram-positive and gram-negative microorganisms, incl. *Actinobacillus pleuropneumoniae*, *Clostridium spp.*, *Escherichia coli (some strains)*, *Staphylococcus spp.*, *Streptococcus spp.*, *Haemophilus spp.*, *Pasteurella spp.*, As well as *Mycoplasma spp.*, *Rickettsia spp.*, *Chlamydia spp.*

2.2 The mechanism of the bacteriostatic action of the antibiotic -it exerts its action by inhibiting the protein synthesis by reversible binding to the 30S ribosomal subunit of microorganisms sensitive to the veterinary product.

2.3 Doxycycline is well absorbed into the bloodstream from the gastrointestinal tract and widely distributed in the organisms. The maximum concentration of the antibiotic in the blood serum is reached after 2-4 hours and is maintained at a therapeutic level for at least 18-24 hours after using the veterinary product.

Doxycycline is excreted primarily in faeces.

2.4 Tylosin is an antibiotic from the macrolide group. It is active against most gram-positive and gram-negative microorganisms, including *Staphylococcus spp.*, *Streptococcus spp.*, *Corynebacterium spp.*, *Erysipelothrix rhusiopathiae*, *Clostridium spp.*, *Escherichia coli (some strains)*, *Klebsiella spp.*, *Proteus spp.*, *Salmonella spp.*, *Campylobacter spp.*, *Bordetella spp.*, *Pasteurella spp.*, *Haemophilus spp.*, and also *Mycoplasma spp.*, *Chlamydia spp.*

2.5 The mechanism of action of tylosin is based on inhibition of protein synthesis in a microbial cell by blocking the enzyme translocase.

2.6 When administered orally, the veterinary product is rapidly absorbed from the gastrointestinal tract and enters all organs and tissues. The highest concentrations of tylosin are found in the lungs, liver, mammary gland and kidneys. The therapeutic concentration of the antibiotic in the blood is maintained for 15-18 hours.

2.7 The veterinary product is excreted from the body mainly in faeces.

3. INDICATIONS FOR USE

3.1 Doxytil is used as a therapeutic agent in calves, piglets and poultry for colibacillosis, salmonellosis, pasteurellosis, bordetellosis, haemophilia, mycoplasmosis, chlamydia and other infectious diseases of the gastrointestinal tract, respiratory organs, genitourinary system caused by microorganisms sensitive to doxycycline and tylosin.

3.2 The veterinary product is administered to animals and poultry orally in group or individually with water for 3-5 days in the following doses, in accordance with the table:

Table – Dosage

Class of Stock	Recommended dose	
	Individually	In groups
Calves	5 g of the veterinary product per 100 kg of animal weight twice a day in water, milk or milk substitute	-----
Pigs	0.5-1.0 g of the veterinary product for 10-15 kg of animal weight	0.5-1.0 kg of the veterinary product per 1000 l of drinking water
Poultry (broiler chickens, replacement hens, laying hens, goslings, turkeys and ducklings)	0.5-1.0 g of the veterinary product per 10 kg of animal weight per day	0.5-1.0 kg of the veterinary product per 1000 l of drinking water

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 reactions, except of cases of individual hypersensitivity to the components of the veterinary product, have not been identified. If symptoms of an allergic reaction appear, the veterinary product is discontinued and, if necessary, symptomatic therapy is prescribed.

3.5 Contraindications. Increased individual sensitivity of animals to the components of the veterinary product. It is forbidden to use animals with severe impaired renal and hepatic function, as well as poultry, the egg of which is used for human consumption.

3.6 The veterinary product should not be used simultaneously with veterinary products containing penicillins, cephalosporins, lincomycin, and iron.

3.7 Slaughtering of pigs and poultry for human consumption is allowed no earlier than 20 days after the last use of the veterinary product.

Meat of animals and poultry, forced to be killed before the expiration of the specified period, can be used as feed for 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 for TrionisVet, LLC, 141092, Russia, Moscow region, Korolev, md. Yubileynyj, st. Lesnaya, 14, office 5.

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

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Veterinary Medicinal Product Council	
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09/01/2020. Minutes No. 105	