

**Summary of Veterinary Product Characteristics  
TILTAR 80**

**1. GENERAL PRODUCT INFORMATION**

- 1.1 Tiltar 80.
- 1.2 Tiltar 80 is a broad-spectrum antimicrobial veterinary product, water-soluble powder from white to yellow with a specific odor for oral solution, 1 g contains 800 mg of tylosin tartrate as an active ingredient and dextrose as an excipient.
- 1.3 The veterinary product is packed in secondary packaging: foil bags of 100, 500, 1000, 5000 and 10000 g.
- 1.4 Tiltar 80 is stored under the requirement of the list B: in a 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.

**2. PHARMACOLOGICAL PROPERTIES**

- 2.1 Tylosin tartrate is an antibiotic of the macrolide group produced by *Streptomyces fradiae*, is active against most gram-positive (*Staphylococcus* spp., *Streptococcus* spp., *Listeria monocytogenes*, *Corynebacterium* spp., *Erysipelothrix rhusiopathiae*, *Clostridium* spp.), *Campylobacter* spp., *Bordetella* spp., *Pasteurella* spp., *Haemophilus* spp.), bacteria, mycoplasma and chlamydia.
- 2.2 The bacteriostatic effect of tylosin is due to the blocking of protein synthesis in the microbial cell due to the connection with the 50S ribosomal subunit and inhibition of the activity of the translocase enzyme.
- 2.3 When administered orally, the veterinary product is rapidly absorbed from the gastrointestinal tract and distributed in the organs, tissues and body fluids. The highest concentration of tylosin is found in the lungs, liver and kidneys. The therapeutic concentration of the antibiotic in the body is maintained for 15-18 hours.
- 2.4 Tylosin tartrate is excreted from the body mainly with feces, to a lesser extent - with urine, in laying birds - with eggs.

**3. DOSAGE AND INDICATION**

- 3.1 Tiltar 80 is used as a therapeutic agent for respiratory mycoplasmosis of chickens, infectious sinusitis of turkeys, as well as pigs with dysentery, gastroenterocolitis of bacterial etiology.
- 3.2 The veterinary product is administered orally individually or in groups with water.
- 3.3 Tiltar 80 is prescribed to poultry in a dose of 0.5 kg of the veterinary product per 1 ton of drinking water, to broilers and replacement young animals for 3-5 days, turkeys - for 5-7 days.
- 3.4 For pigs, the veterinary product is used at the dose of 0.25 kg of the veterinary product per 1 ton of drinking water (or 5 mg of the veterinary product per 1 kg of live weight) for 3-10 days.
- 3.5 The veterinary product is preliminarily dissolved in a small amount of water, adding water to the veterinary product, and then the volume of the solution is brought to the drinking rate.
- 3.6 During the period of treatment, animals 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. It is possible to drink the daily dose of the veterinary product by the pulse dosing method for 4-6 hours.
- 3.7 Tiltar 80 can be used with emeriostatics.
- 3.8 Adverse effects, with the exception of cases of individual hypersensitivity to the component of the medicinal 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.
- 3.9 Simultaneous use of the veterinary product with penicillins, cephalosporins, lincomycin or other macrolides is not allowed, as this can reduce the antibacterial effect of tylosin.

3.10 Contraindications. The use of the veterinary product is contraindicated in case of hypersensitivity to tylosin tartrate, with severe renal and hepatic insufficiency. It must not be used in poultry, whose eggs are used for human consumption, turkeys and replacement chickens less than two weeks before the start of egg-laying.

3.11 Slaughtering of animals and poultry for human consumption is allowed no earlier than 10 days after the last use of the antibiotic.

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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