APPROVED
Veterinary Medicinal Product Council
Minutes No. 104 dated October 25, 2019

Summary of Veterinary Product Characteristics
TILMICOSIN 30% AQUA-TRV

1. GENERAL PRODUCT INFORMATION

1.1 Tilmicosin 30% aqua-TRV.

1.2 Tilmicosin 30% aqua- TRV is an antibacterial product, oral solution from light yellow to yellow-brown, may be a slight precipitate, 1 ml contains 300 mg of tilmicosin and excipients - phosphoric acid, propylene glycol, benzyl alcohol, highly purified water.

1.3 The veterinary product is packed in polymer containers of 100, 500, 1000, 2000, 3000, 5000 and 10000 ml with screw tamper resistant caps.

1.4 Tilmicosin 30% aqua-TRV 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 three years from the date of manufacture, subject to storage and transportation conditions. The shelf life once opened is 28 days.

2. PHARMACOLOGICAL PROPERTIES

2.1 Tilmicosin 30% aqua-TRV belongs to antibacterial veterinary products of the macrolide group and has a broad spectrum of antimicrobial activity. It is compatible with sulfonamides, tetracyclines, nitrofurans, spectinomycin and coccidiostatics. Active against most gram-positive and some gram-negative microorganisms, including: gram-positive: aerobic cocci - *Staphylococcus spp., Streptococcus spp*.; anaerobic spore-forming bacteria - *Clostridium spp*.; facultative anaerobes - *Arcanobacterium spp*,, gram-negative: aerobic bacteria - *Pasteurella spp.*, and *Chlamydia spp., Actinobacillus pleuropneumonia, Mannheimia haemolytica, Brachyspira hyodysenteriae and Mycoplasma spp*.

2.2 The mechanism of bacteriostatic action of tilmicosin is to block protein synthesis in a bacterial cell at the ribosomal level, as a result of the formation of a complex with the 508-subunit of ribosomes, but at high concentrations it can act as bactericidal agent.

2.3 Tilmicosin is intracellularly capable of penetrating and accumulating in alveolar macrophoges. Its concentration in the tissues of the respiratory system is 40 times higher than the MIC for mycoplasmas. Tilmicosin phosphate binds moderately to plasma proteins (less than 30%), which ensures its high degree of solubility in lipids and allows it to penetrate well into biological fluids and tissues.

2.4 After oral administration, tilmicosin is well absorbed in the gastrointestinal tract and penetrates into most organs and tissues of the body, reaching the highest concentrations in the lungs and blood serum after 2-3 hours, and is maintained at a therapeutic level for 18-24 hours. It is metabolized in the liver and excreted from the body of animals mainly unchanged, and partly in the form of metabolites with feces and partly with urine.

2.5 Tilmicosin 30% aqua-TRV, according to the degree of exposure is classified as a moderately hazardous substance (hazard class 3 according to GOST 12.1.007-76).

3. DOSAGE AND INDICATION

3.1 Tilmicosin 30% aqua-TRV is used as a therapeutic agent in poultry, pigs and calves with mycoplasmosis and respiratory diseases, as well as mixed infections, secondary infections in viral diseases and other animal diseases, the causative agents of which are sensitive to tilmicosin..

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**
broiler chickens, replacement	0.05-0.07 ml per 1 kg of poultry weight (15-21 mg of active substance per 1 kg	250 ml of preparation per 1000 liters of drinking water for 3 days

chickens, parent stock, turkeys, geese, ducks	of body weight) for 3 days	
pigs	0.05-0.07 ml per 1 kg of animal weight (15-21 mg of active substance per 1 kg of body weight) for 5 days	500-700 ml of the veterinary product per 1000 liters of drinking water for 5 days
calves	0.04 ml per 1 kg of animal weight (12 mg of active substance per 1 kg of body weight) for 3-5 days with water, milk or milk replacer	----------

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.

The decrease in appetite, a decrease in water intake, a decrease in body weight and anorexia may appear in case of veterinary product overdose in animals.

3.5 Contraindications. The use of the veterinary product is contraindicated in case of hypersensitivity to antibiotics of the macrolide group, with severe renal and hepatic insufficiency.

Must not use the veterinary product for poultry whose eggs are used for human consumption, and replacement chickens at least 2 weeks before the start of the ovipositor and animals during pregnancy, calves over three months of age, pregnant and lactating animals.

3.6 The veterinary product should not be used simultaneously with other veterinary products of the macrolide group and with bactericidal antibiotics, within 7 days before and 7 days after the use of ionophore coccidiostatics, aminoglycoside antibiotics, due to the possible occurrence of adverse effects and complications in animals (diarrhea, anorexia, paresis, nephrotoxic effects). In order to prevent adsorption and reduce antibacterial activity, the veterinary product should not be used simultaneously with veterinary products and feed supplements containing bentonite.

3.7 Slaughtering of poultry for human consumption is allowed no earlier than 12 days after the last administration of the veterinary product, pigs - no earlier than 14 days; calves - not earlier than 42 days after the last administration of the veterinary product.

The 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

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
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