APPROVED
Veterinary Medicinal Product Council
Minutes No. 102 dated June 19, 2019

Summary of Veterinary Product Characteristics
OXYTETRACYCLINE 100-TRV

1. GENERAL PRODUCT INFORMATION

1.1 Oxytetracycline 100-TRV.

1.2 Oxytetracycline 100-TRV is an antimicrobial preparation for oral use, yellow powder, without impurities, 1 g contains 900 mg of oxytetracycline hydrochloride as an active ingredient and an excipient - dectrose.

1.3 The product is packed in foil bags of 100, 500, 1000, 5000 and 10000 g and in multilayer paper bags with a polyethylene insert of 10, 20, 25, 30 kg. Polyethylene bags liners must be packed hermetically.

1.4 Oxytetracycline 100-TRV is stored according to list B in a dry, dark place at a temperature from 0 ° C to plus 25 ° C. The shelf life in the manufacturer's packaging, subject to the shelf life of three years from the date of manufacture, the shelf life of once opened product is 35 days

2. PHARMACOLOGICAL PROPERTIES

2.1 Oxytetracycline hydrochloride belongs to the derivatives of tetracycline antibiotics.

2.2 Oxytetracycline hydrochloride has a broad spectrum of antimicrobial action, effective against gram-positive microorganisms: *Staphylococcus spp., Streptococcus spp., Corynebacterium spp., Clostridium spp., Erysipelothrix rhusiopathiae, Actynomyces spp.* and etc.; and gram-negative: *Escherichia coli, Pasteurellas pp., Salmonella spp., Brucella spp.* and etc.; rickettsia, chlamydia and mycoplasma, protozoa (anaplasma, leptospira, spirochetes).

The veterinary product is especially effective against *Escherichia coli and Salmonella spp.*

2.3 The mechanism of action of oxytetracycline hydrochloride is to inhibit protein synthesis of bacterial cells by blocking the binding of aminoacyl-tRNA to the OS subunit of ribosomes.

2.4 Oxytetracycline hydrochloride is well absorbed into the bloodstream from the gastrointestinal tract and is rapidly distributed in the organs and tissues of the body. The maximum concentration in blood plasma is reached within 1-2 hours after administration of the veterinary product and remains at a therapeutic level for 10-12 hours.

2.5 Oxytetracycline hydrochloride is practically not metabolized and is excreted from the body mainly with feces, partly with urine.

2.6 Oxytetracycline 100-TRV belongs to low-hazard substances (hazard class 4 according to GOST 12.1.007-76) according to its exposure.

3. DOSAGE AND INDICATION

3.1 Oxytetracycline 100-TRV is used in cattle and small ruminants, pigs, poultry, horses as a therapeutic agent for diseases of the respiratory, genitourinary system, gastrointestinal tract, septic conditions, secondary diseases of bacterial etiology: colibacillosis, salmonellosis, pasteurellosis, staphylococcal infection pig erysipelas, rickettsiosis, chlamydia, respiratory mycoplasmosis and other diseases caused by pathogens sensitive to oxytetracycline hydrochloride.

3.2 The veterinary product is administered orally with water or feed during or after feeding-2 times a day for 5-7 days in the following doses, in accordance with the table

Table - Doses of the veterinary product.

Animal species	Recommended dose
horses	5-8 mg per 1 kg of body weight
cattle	10-20 mg per 1 kg of body weight
small ruminants	10-30 mg per 1 kg of body weight

pigs	15-30 mg per 1 kg of body weight
poultry	20-40 mg per 1 kg of body weight

3.3 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, the veterinary product is discontinued and, if necessary, symptomatic therapy is started, antihistamines and calcium preparations. With prolonged use of the veterinary product, candidiasis may develop.

3.4 Contraindications. The use of the veterinary product is contraindicated in case of animal hypersensitivity to tetracycline antibiotics. Do not use the veterinary product simultaneously with antibiotics of the penicillin and cephalosporin groups. In case of overdose, there may be a decrease in appetite, depression, vomiting and diarrhea.

3.5 It must not be used in pregnant animals, replacement chickens less than 20 days before the start of egg-laying.

3.6 Slaughter of animals and poultry for meat is allowed no earlier than 20 days after the last administration of the veterinary product.

The meat of animals and poultry, forced to be killed before the expiration of the specified period, can be used to feed carnivores.

3.7 Milk from lactating animals and poultry eggs must not be used for food purposes within 20 days after the last administration of the veterinary product.

Before the expiration of the specified period, milk is drunk to animals after heat treatment.

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 TrionisVet, 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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Approved
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