

## Summary of Veterinary Product Characteristics

### Enrofloxacin 20-TRV

#### 1. GENERAL PRODUCT INFORMATION

1.1 Enrofloxacin 20-TRV.

1.2 Enrofloxacin 20-TRV is an antibacterial veterinary product, white to light yellow powder without impurities, each g contains 200 mg of enrofloxacin and excipients (dextrose).

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

1.4 Enrofloxacin 20-TPV is stored according to list B in a dry, dark place at a temperature from 0 ° C to plus 25 ° C. Shelf life, subject to storage conditions in a closed manufacturer's packaging - three years from the date of manufacture, after opening the package -35 days

#### 2. PHARMACOLOGICAL PROPERTIES

2.1 Enrofloxacin, active substance of the veterinary product, belongs to the group of 3rd generation fluoroquinolones and has a wide spectrum of antibacterial action, is active against gram-positive and gram-negative bacteria, including *Escherichia coli*, *Haemophilus* spp., *Salmonella* spp., *Klebsiella* spp. , *Pasteurella multocida*, *Pseudomonas* spp., *Bordetella* spp., *Campylobacter* spp., *Corynebacterium* spp., *Staphylococcus* spp., *Streptococcus* spp., *Actinobacillus* spp., *Clostridium* spp., *Bacteroides* spp., *Fusobacterium necrophorum* and *Mycoplasma* spp. Bacterial resistance to enrofloxacin develops relatively slowly.

2.2 The mechanism of the antimicrobial action of enrofloxacin is to inhibit the activity of the enzyme gyrase, which affects the replication of the DNA helix in the nucleus of the bacterial cell.

2.3 Enrofloxacin is well and quickly absorbed from the gastrointestinal tract and penetrates into all organs and tissues of the body. The maximum concentration of the veterinary product in the blood is reached 1-2 hours after the administration of the veterinary product and lasts for 6 hours, and the therapeutic concentration - for 24 hours. It is excreted from the body mainly unchanged in urine and in small quantities in faeces, in poultry - in droppings.

2.4 Enrofloxacin 20-TPV, according to the exposure degree, refers to substances of low hazard (hazard class 4 according to GOST 12.1.007-76).

#### 3. INDICATIONS FOR USE

3.1 Enrofloxacin 20-TPV is used as a therapeutic agent in pigs and poultry for respiratory and gastrointestinal diseases of bacterial etiology, including colibacillosis, salmonellosis, pasteurellosis, necrotic enteritis, atrophic rhinitis, hemophilosis, mycoplasmosis, staphylococcosis, streptococcosis, as well as coinfections and secondary infections, the causative agents of which are sensitive to enrofloxacin.

3.2 The veterinary product is administered orally with drinking water or feed once a day for 3-5 days in the following doses, in accordance with the table.

Table - Doses of the veterinary product

Class of Stock	Recommended dose	
	With Feed	With water

Poultry	0.5 kg of the veterinary product per ton of feed	0.5 kg of the veterinary product per ton of water
Pigs	0.0125 - 0.025 g of the veterinary product (2.5-5 mg of API) per 1 kg of body weight	-----
For treatment of salmonellosis and in severe cases of swine disease, the dose of the veterinary product is doubled		

3.3 During the period of treatment, 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 Skipping of the next dose of the veterinary product should be avoided, this can lead to a decrease in therapeutic efficacy. If one dose is missed, the use of the veterinary product is resumed in the same dosage and according to the same scheme.

3.5 Enrofloxacinum 20-TPV does not cause adverse reactions in recommended doses. In case of allergic reactions, the veterinary product is discontinued and antihistamines (diphenhydramine, allergic) and calcium preparations (calcium chloride, calcium gluconate calcium borogluconicum) are prescribed.

3.6 Should not use the veterinary product for laying hens, whose eggs are used for human consumption, replacement chickens at least two weeks before the start of oviposition, ruminants with developed cicatricial digestion, animals with renal and hepatic insufficiency, as well as with hypersensitivity to fluoroquinolones

3.7 Simultaneous use of the veterinary product with amphenicol, macrolides, tetracyclines, theophylline and non-steroidal anti-inflammatory veterinary products is not allowed.

3.8 Slaughtering of pigs for human consumption is allowed no earlier than 14 days; poultry - not earlier than 12 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.

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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