

Summary of Veterinary Product Characteristics

Enrofloxacin 20% aqua-TRV

1. GENERAL PRODUCT INFORMATION

- 1.1 Enrofloxacin 20% aqua-TRV.
- 1.2 Enrofloxacin 20% aqua-TRV - antibacterial preparation in the form of oral solution -clear slightly yellow colour, each ml contains 200 mg of enrofloxacin and excipients - potassium hydroxide, Trilon B, benzyl alcohol, highly purified water.
- 1.3 The veterinary product is packed in a polymer container of appropriate capacity with screw tamper proof caps of 100; 500; 1000; 2000; 3000, 5000 and 10000 ml.
- 1.4 The veterinary product is stored according to list B in a dry, dark place at a temperature from + 5 ° C to + 25 ° C. The shelf life, subject to storage conditions in the manufacturer's sealed packaging, is two years from the date of manufacture, after opening the packaging - 28 days.

2. PHARMACOLOGICAL PROPERTIES

- 2.1 Enrofloxacin 20% aqua-TRV is a broad-spectrum antibacterial veterinary product providing a wide spectrum of antimicrobial and antimycoplasma activity.
- 2.2 Enrofloxacin - belongs to the 3rd generation fluoroquinolones, is a quinol carboxylic acid derivative, the mechanism of action is to inhibit the activity of the enzyme gyrase, which affects the replication of the DNA helix in the nucleus of a bacterial cell, leads to disruption of protein synthesis and suppression of the growth and development of gram-positive and gram-negative bacteria, including: gram-positive: aerobic cocci - Staphylococcus spp., Streptococcus spp .; anaerobic spore-forming bacteria - Clostridium spp .; gram-negative: aerobic bacteria - Escherichia coli, Haemophilus spp., Salmonella spp., Pasteurella spp., Bordetella spp., as well as Corynebacterium spp., Campylobacter spp., Pseudomonas spp., Proteus spp., Mycoplasma spp.
- 2.3 Enrofloxacin is well and quickly absorbed in the gastrointestinal tract and penetrates into all organs and tissues of animals, is excreted from the body mainly unchanged, mainly in urine and in small quantities with faeces, in poultry – in droppings.
- 2.4 The veterinary product, according to the exposure degree, belongs to low-hazard substances (hazard class 4 according to GOST 12.1.007-76).

3. INDICATIONS FOR USE

- 3.1 Enrofloxacin 20% aqua-TRV is used as a therapeutic agent in cattle and small ruminants, pigs, poultry for respiratory and gastrointestinal diseases of bacterial etiology, including colibacillosis, salmonellosis, pasteurellosis, necrotizing enteritis, hemophilosis, campyloplasmosis , staphylococcosis, as well as coinfections and secondary infections in viral diseases, the causative agents of which are sensitive to enrofloxacin.
- 3.2 The veterinary product is administered orally with drinking water individually or in groups for 3-5 days in the following doses, in accordance with the table.

Table - Doses of the veterinary product

Class of Stock	Recommended dose
Calves, Lambs, Pigs	Individually 0.0125-0.025 ml of the veterinary product per 1 kg of animal weight (according to API - 2.5-5 mg per 1 kg of animal weight)
Poultry up to 4 weeks of birth	Group method 250 ml of the veterinary product per 1000 l of drinking water

Poultry after 4 weeks of birth	Group method 500 ml of the veterinary product per 1000 l of drinking water
The clinical signs associated with salmonellosis, the veterinary product is used in a double therapeutic dose (calves, lambs, pigs 0.025-0.05 ml / kg; poultry 500-1000 ml per 1000 l of drinking water).	

3.3 During the period of treatment, animals 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.

3.5 Adverse reactions, with the exception of cases of individual hypersensitivity to the components of the veterinary product, have not been identified. In case of symptoms of an allergic reaction in animals, the veterinary product is discontinued and, if necessary, symptomatic therapy is prescribed.

3.5 Contraindications. The use of the veterinary product is contraindicated in case of hypersensitivity to fluoroquinolones, with severe renal and hepatic insufficiency. Is forbidden to use the veterinary product in poultry, whose eggs are used for human consumption and replacement chickens at least two weeks before the start of oviposition, for ruminants with developed cicatricial digestion.

3.6 The veterinary product should not be used simultaneously with macrolides, tetracyclines, theophylline and non-steroidal anti-inflammatory veterinary products.

3.7 Slaughtering of animals and poultry for human consumption is allowed no earlier than 14 days after the last use of the veterinary product.

Meat of animals and poultry, forcedly 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).

[Stamp]:

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]
June 19, 2019. Minutes No. 102	