

**Summary of Veterinary Product Characteristics  
TRIENROKOL AQUA**

**1. GENERAL PRODUCT INFORMATION**

1.1 Trienrokol aqua.

1.2 Trienrokol aqua is a complex antibacterial veterinary product, solution from light yellow to brown, 1 ml contains 100 mg of enrofloxacin, 50 mg of trimethoprim and 1 000 000 IU of colistin sulfate as active ingredients and excipients - propylene glycol, citric acid, lactic acid, highly purified water.

1.3 The veterinary product is packed in polymer containers (polyethylene, polymer bottles or polyethylene canisters of appropriate capacity with screw tamper resistant caps) of 100, 500, 1000, 2000, 3000, 5000 and 10000 ml.

1.4 Trienrokol aqua 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 two years from the date of manufacture, subject to storage conditions.

**2. PHARMACOLOGICAL PROPERTIES**

2.1 Trienrokol aqua is a complex antimicrobial veterinary product of a wide spectrum of action, the therapeutic effect is the influence of the active ingredients of the veterinary drug: enrofloxacin, trimethoprim and colistin sulfate, which exhibit synergistic joint action, providing a wide range of antimicrobial activity against gram-positive and gram-negative microorganisms.

2.2 Enrofloxacin belongs to the 3rd generation of fluoroquinolones, is a derivative of quinol carboxylic acid, 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, which leads to damage of protein synthesis and suppression of growth and development gram-positive and gram-negative bacteria, including:

- gram-positive: aerobic cocci - *Staphylococcus spp.*, *Streptococcus spp.*; anaerobic spore-forming bacteria - *Clostridium perfringens*;
- gram-negative: aerobic bacteria - *Escherichia coli*, *Haemophilus spp.*, *Salmonella spp.*, *Bordetella spp.* ;
- as well as *Campylobacter spp.*, *Corynebacterium pyogenes*, *Pseudomonas aeruginosa* and *Mycoplasma spp.*

2.3 Colistin sulfate is a peptide antibiotic of the polymyxin group, the antibacterial activity of which extends mainly to the gram-negative microflora, its mechanism of action is associated with a violation of the permeability of the cytoplasmic membrane of bacteria sensitive to it, is synthesized by the aerobic spore-forming bacillus *Bacillus polymyxa* and has a pronounced bactericidal effect in relation to most aerobic gram-negative microorganisms, including:

- gram-negative: aerobic bacteria - *Escherichia coli*, *Salmonella spp.*; *Pasteurella spp.*, *Bordetella spp.*;
- as well as *Klebsiella spp.*, *Pseudomonas aeruginosa*.

2.4 Trimethoprim is active against a wide range of microorganisms, including gram-positive and gram-negative bacteria:

- gram-positive: aerobic cocci - *Staphylococcus spp.*, *Streptococcus spp.*; anaerobic spore-forming bacteria - *Clostridium spp.*;
- gram-negative: aerobic bacteria - *Escherichia coli*, *Klebsiella spp.*, as well as *Proteus spp.*;
- as well as chlamydia, nocardia (actinomycetes), some mycobacteria, protozoa and many anaerobic bacteria.

The action against gram-negative bacteria extends to *Haemophilus parainfluenzae*, *Haemophilus ducreyi*, *Citrobacter freundii* and others, *Klebsiella oxytoca* and others, *Enterobacter cloacae*, *Serratiamarcescens*, etc.

2.5 The mechanism of action of trimethoprim is associated with inhibition of the enzyme dihydrofolate reductase, during the formation of tetrahydrofolic acid. This leads to depletion of folate, the main cofactor

of nucleic acid synthesis, as a result, the production of nucleic acids and bacterial protein is disrupted. With simultaneous use with sulfonamides, a synergistic effect is noted in relation to the suppression of the production of tetrahydrofolic acid.

2.6 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 the urine and in small quantities with feces.

Colistin sulfate is practically not absorbed in the gastrointestinal tract, does not accumulate in organs and tissues, it is excreted from the body mainly unchanged with feces.

Trimethoprim is absorbed in the gastrointestinal tract quickly and almost completely, the maximum concentration is reached after 1-4 hours. Trimethoprim crosses the placenta and is excreted in milk, excreted from the body mainly unchanged.

### 3. DOSAGE AND INDICATION

3.1 Trienrokol aqua is used as a therapeutic agent for respiratory and gastrointestinal infections of bacterial etiology caused by microorganisms sensitive to enrofloxacin, trimethoprim, colistin and their combinations.

3.2 The veterinary product is administered orally with drinking water, individually or in groups, once a day in the following doses, in accordance with the table:

Table - Doses of the veterinary product

Animal species	Recommended dose	
	individually	in groups
calves	0.25-0.5 ml per 10 kg of body weight for 5 days with milk or water	-----
pigs	0.3 ml per 10 kg of body weight for 3-5 days; with a severe form of the disease, the dose is increased to 0.5 ml per 10 kg of animal weight; before use, the veterinary product is diluted in a 1: 1 ratio with water	1 liter per 3000 liters of drinking water
poultry	0.1 ml per 1 kg of body weight for 5 days	0.5 liters per 1000 liters of drinking water for 5 days

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.

3.5 Contraindications. The use of the veterinary product is contraindicated in case of hypersensitivity to enrofloxacin, trimethoprim and colistin, with severe renal and hepatic insufficiency and in animals with signs of diseases of the central nervous system and with impaired development of cartilage and bone tissues. It must not be used in poultry, whose egg is used as food for humans, pregnant and suckling sows.

3.6 The veterinary product should not be used simultaneously with non-steroidal anti-inflammatory veterinary products, macrolide antibiotics, and tetracycline.

3.7 Slaughter of pigs and calves for meat is allowed no earlier than 15 days, poultry - no earlier than 12 days after the last administration of the veterinary product.

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

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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]
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