APPROVED
Veterinary Medicinal Product Council
dated March 14, 2019 Minutes No. 100

Summary of Veterinary Product Characteristics

Enrotrim aqua

1. GENERAL PRODUCT INFORMATION

1.1 Enrotrim aqua.

1.2 Enrotrim aqua –is an antibacterial preparation, dosage form – oral solution, clear, slightly yellowish to brown solution, each ml contains 100 mg of enrofloxacin and 50 mg of trimethoprim as active substances and excipients - propylene glycol, lactic acid, citric 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 proof caps) of 100, 500, 1000, 2000, 3000, 5000 and 10000 ml.

1.4 Enrotrim aqua is stored with precautions according to list B in a dry, dark place at a temperature from + 5 ° C to + 25 ° C. Shelf life is two years from the date of manufacture, subject to storage conditions.

2. PHARMACOLOGICAL PROPERTIES

2.1 Enrotrim aqua is a combined broad-spectrum antibacterial veterinary product, the antibacterial effect is due to the synergism of the action of trimethoprim and enrofloxacin against gram-positive and gram-negative microorganisms.

2.2 Enrofloxacin belongs to the group of fluoroquinolones. It has a wide spectrum of antibacterial and including antimycoplasma action, inhibits the growth and development of gram-positive and gram-negative bacteria, incl. Escherichia coli, Haemophilus spp., Pasteurella spp., Salmonella spp., Staphylococcus spp., Streptococcus spp., Clostridium spp., Leptospira spp., Actinobacterium spp., Bordetella spp., Compylobacter spp., Somonium spp. , Rickettsia spp., Proteus spp., Mycoplasma spp.

The mechanism of action of enrofloxacin on a bacterial cell is based on blocking protein synthesis by inhibiting bacterial DNA gyrase, which leads to disruption of DNA synthesis in microbial cell

Enrofloxacin is well and rapidly absorbed from the gastrointestinal tract and is distributed in organs and tissues. Therapeutic concentrations are achieved after 1 -1.5 hours after administration and persist for 24 hours.

2.3 Trimethoprim is a broad-spectrum antimicrobial agent from the group of diaminopyrimidines. Trimethoprim has an antimicrobial effect on gram-positive and gram-negative microorganisms: Escherichia coli, Salmonella spp., Pasteurella spp., Enterobacter spp., Proteus spp., Staphylococcus spp., Streptococcus spp., Haemophilus spp., Chlamstidium spp. spp., Actinobacterium spp., Bordetella spp., Compylobacter spp., Corynebacterium spp., Pseudomonas spp., Rickettsia spp., Mycoplasma spp., and also acts on Toxoplasma and Eimeria.

The mechanism of action is associated with the inhibition of bacterial dihydrofolic acid reductase.

It is metabolized in the liver and excreted mainly in urine. Concentration in urine is much higher than in blood. The half-life is 8-10 hours

3. INDICATIONS FOR USE

3.1 Enrotrim aqua is used is used as a therapeutic agent in poultry (broiler chickens, replacement young laying hens, goslings, turkey poultry and ducklings) for treatment: colibacillosis, salmonellosis, necrotic enteritis, streptococcosis, mycoplasmosis, etc.

3.2 The veterinary product is administered orally in drinking water individually or in a group way for 3-5 days in the following doses, in accordance with the table:

Table - Veterinary product dosage

Class of Stock	Recommended dose
Poultry (broiler chickens, replacement laying hens, goslings, turkeys and ducklings)	0.5-1 ml per 1 litter of drinking water

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 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. Long-term treatment may result in dysbiosis onset.
3.5 Contraindications. The use of the veterinary product is contraindicated in case of hypersensitivity to the components of the veterinary product, with severe renal and hepatic insufficiency. It is forbidden to use in poultry, whose eggs are used for human consumption.
3.6 The veterinary product should not be used simultaneously with antibiotics of the macrolide group, tetracyclines, sulphonamides.
3.7 Slaughtering of 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 Centre" (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 for TrionisVet, LLC, 141092, Russia, Moscow region, Korolev, md. Yubileynyj, st. Lesnaya, 14, office 5.
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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