

Summary of Veterinary Product Characteristics
Enromol aqua-TRV

1. GENERAL PRODUCT INFORMATION

1.1 Enromol aqua-TRV.

1.2 Veterinary medicinal product Enromol aqua-TRV is a complex antibacterial solution for use in drinking water, dosage form - light yellow to yellow, weak opalescence solution, slightly viscous at room temperature, each ml contains 100 mg of enrofloxacin and 2 000 000 ME colistin sulphate as active substances and excipients - propylene glycol, lactic acid, benzyl alcohol, highly purified water.

1.3 The drug 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 Enromol aqua - TPV is stored according to list B in a dry, dark place at a temperature of +5 ° C to + 25 ° C. Shelf life is two years from the date of manufacture, subject to storage conditions.

After the end of the storage period, any unused veterinary medicinal product should be disposed of in accordance with local requirements.

2. PHARMACOLOGICAL PROPERTIES

2.1 Enromol aqua-TRV is a complex broad-spectrum antimicrobial drug containing enrofloxacin and colistin sulphate, exhibit synergistic action to provide a broad spectrum of antimicrobial activity against gram-positive and gram-negative microorganisms.

2.2 Enrofloxacin - belongs to the 3rd generation fluoroquinolones, is a quinol carboxylic acid derivative, the mechanism of action is associated with inhibition the activity of the enzyme gyrase, which affects the replication of the DNA helix in the nucleus of a bacterial cell, which leads to disruption of protein synthesis and suppression of the growth of 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.*, and also *Campylobacter spp.*, *Corynebacterium pyogenes*, *Pseudomonas aeruginosa* u *Mycoplasma spp.*

2.3 Colistin sulphate is a peptide antibiotic of the polymyxin group, the antibacterial activity extends mainly to gram-negative microflora, its mechanism of action is associated with disruption of cytoplasmic membrane permeability of the sensitive bacteria, synthesized by the aerobic spore-forming bacillus *Bacillus polymyxa* and has a pronounced bactericidal effect against most aerobic gram-negative microorganisms, including *Escherichia coli*, *Salmonella spp.*, *Pasteurella spp.*, *Bordetella spp.*, *Klebsiella spp.*, *Pseudomonas aeruginosa*.

2.4 Enrofloxacin is well and rapidly absorbed in the gastrointestinal tract and penetrates into all organs and tissues of animals, is excreted from the body mainly unchanged, in urine and in small quantities in faeces.

2.5 Colistin sulphate is practically not absorbed in the gastrointestinal tract, does not accumulate in organs and tissues, and is excreted from the body mainly unchanged with faeces.

2.6 The veterinary drug Enromol aqua-TRV, according to the exposure degree, belongs to the IV class of hazard (low-hazard substances according to GOST 12.1.007-76).

3. INDICATIONS FOR USE

3.1 Enromol aqua-TRV is used as a therapeutic agent for treatment of respiratory and gastrointestinal infections of bacterial ethology, including colibacillosis, salmonellosis, enteritis, mycoplasmosis and other diseases in pigs, cattle and ruminants, poultry (broiler chickens, breeding and rearing flocks, turkeys), as well as for concurrent and secondary infections, if the causative agents are sensitive to enrofloxacin and colistin.

3.2 The drug is administered orally with drinking water 1 time per day, individually or in groups for 3-5 days in the following doses, in accordance with the table.

Table - Doses of the drug

Class of Stock	Recommended dose	
	Individually	Group method
Piglets	0.3 ml of the drug per 10 kg of body weight or with drinking water 0.5 ml per 1 l of drinking water	-----
Calves, lambs	0.025-0.05 ml of the drug per 1 kg of body weight	-----
Poultry (broiler chickens, breeding and rearing flocks, turkeys)	0.5-1 ml of the drug per 1 l of drinking water	0.5 - 1 l per 1000 l of drinking water

With an individual method of use, the required amount of the drug is diluted in a 1: 1 ratio with 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 drug, have not been identified. In case of symptoms of an allergic reaction in animals, the drug is discontinued and, if necessary, symptomatic therapy is prescribed.

3.5 The use of the drug is contraindicated in case of hypersensitivity to fluoroquinolones and polymyxins, with severe renal and hepatic insufficiency. It is forbidden to use the drug for poultry, whose egg is used for human consumption.

3.6 The drug should not be used simultaneously with bacteriostatic antibiotics (tetracyclines, macrolides and chloramphenicol), theophylline, steroids, indirect anticoagulants.

3.7 Slaughtering of animals for human consumption is allowed no earlier than 14 days after the last use of the drug; poultry - not earlier than 11 days after the last use of the drug.

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 drug.

5 CLAIMING PROCEDURE

5.1 In case of complications after the use of the drug, 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 drug in accordance with the instructions. After the confirmation of a drug adverse effect to the animal, the veterinary specialists take samples in the required amount for laboratory tests, at least three unopened vials of the drug 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

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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