

**Instructions
for use of the veterinary drug
Tetraflex Aqua**

1 General information

1.1 Tetraflex Aqua (Tetraflexum aqua).

International non-proprietary name of the active pharmaceutical ingredients: tilmicosin, levofloxacin, trimethoprim.

1.2 The drug is light yellow to dark yellow liquid. A slight precipitation is allowed.

Dosage form: oral solution.

1.3 1 ml of the drug contains 50 mg of tilmicosin, 25 mg of levofloxacin, 25 mg of trimethoprim, excipients (sodium formaldehyde sulfoxylate, EDTA disodium salt, acetic acid) and solvent (purified water).

1.4 The drug is packaged in a 100.0; 500.0 ml and 1.0; 3.0; 5.0; 10.0; 15.0; 20.0; 25.0 l polymer package.

1.5 The drug is stored in the manufacturer's packaging according to list B, in a dry, dark place at a temperature of plus 5°C to plus 25°C.

1.6 Expiration date is two years from the date of manufacturing, subject to the conditions of storage and transportation. After the first opening of the package - not more than 7 days. Do not use after the expiration date. The unused drug is disposed of in accordance with legal requirements.

2 Pharmacological properties

2.1 The active substances of the drug complement each other, thereby expanding the spectrum of antimicrobial activity.

The combination of active ingredients is highly active against gram-negative (*Mycoplasma* spp., *Campylobacter* spp., *Enterobacter* spp., *Escherichia coli*, *Haemophilus* spp., *Klebsiella* spp., *Pasteurella* spp., *Proteus* spp., *Pseudomonas* spp., *Salmonella* spp., *Rickettsia* spp., *Bordetella* spp., *Ornithobacterium rhinotracheale*) and gram-positive microorganisms (*Staphylococcus* spp., *Streptococcus* spp., *Enterococcus* spp., *Mycobacterium* spp., *Clostridium* spp., *Listeria monocytogenes*, *Corynebacterium* spp.)

2.2 Tilmicosin is a semi-synthetic broad-spectrum macrolide antibiotic. The mechanism of antimicrobial effect is to block protein synthesis in the microbial cell at the ribosomal level.

Levofloxacin is a synthetic broad-spectrum antimicrobial bactericidal agent from fluoroquinolones group. The mechanism of action is associated with the blockade of DNA gyrase and topoisomerase IV, impaired supercoiling and cross-linking of deoxyribonucleic acid breaks, inhibition of deoxyribonucleic acid synthesis, and profound metabolic changes in the cytoplasm, cell wall and membranes.

Trimethoprim is an antibacterial agent from diaminopyrimidines group. The mechanism of action is to inhibit bacterial dihydrofolate reductase.

2.3 All components of the drug have high bioavailability; after oral administration, they are quickly absorbed from the gastrointestinal tract and penetrate into most organs and tissues. The maximum concentration in blood serum is reached in 1-2 hours, the therapeutic concentration is preserved for 24-48 hours. The active ingredients of the drug are excreted from the body in the form of metabolites and unchanged with urine and bile.

3 Method of administration

3.1 The drug is used to treat pigs and poultry in case of diseases caused by microorganisms sensitive to the active ingredients of the drug.

The drug is prescribed for diseases of the respiratory system, gastrointestinal tract, genitourinary system; in case of colibacillosis, pasteurellosis, salmonellosis, staphylococcosis, streptococcosis, necrotic enteritis, dysentery, hemophilia, ornithobacteriosis, mycogylasmosis, chlamydia and other diseases.

3.2 The drug is administered orally with drinking water for 3-5 days in the following doses:

- pigs - 0.25-0.5 ml per 1 kg of animal body weight. Group method - 1-2 l of the drug per 1 ton of water;

- for poultry (broiler chickens, replacement chickens, turkeys, geese, ducks) - 0.25-0.5 ml per 1 kg of bird body weight. Group method - 1-2 liters of the drug per ton of water.

3.3 For group administration, pigs and poultry shall receive only water containing the drug. The prepared solution of the drug must be used within 24 hours. When preparing the stock solution, the drug is added to water.

3.4 In the recommended doses, the drug does not cause adverse events. In case of allergic reactions, the drug is discontinued and antihistamines and symptomatic therapy is prescribed.

3.5 Use is contraindicated in animals with increased individual sensitivity to the components of the drug. The drug is not used in animals with impaired renal and hepatic functions, as well as in pregnant animals.

It is forbidden to use the drug in combination with bacteriostatic antibiotics (amphenicols, aminoglycosides, penicillins and tetracyclines), ionophoric eimeriostatics, theophylline, non-steroidal anti-inflammatory drugs, magnesium and calcium drugs.

3.6 The drug is prohibited for use in birds, if their eggs are used as food for humans, as well as replacement young chickens, if their eggs will be used for food, less than two weeks before the start of egg laying.

3.7 Slaughter of pigs for meat is allowed no earlier than 14 days, birds - 12 days after the last use of the drug. The meat of animals and birds forced to be killed earlier than the specified period, is used to feed carnivores.

4 Preventive measures

4.1 When working with the drug, personal hygiene measures and safety regulations shall be observed.

5 Claim procedure

5.1 In case of complications after the use of the drug, its administration is discontinued, and the consumer shall contact the State Veterinary Institution according to the location.

Veterinary specialists of this institution shall study the compliance with all the rules for the use of the drug in accordance with the instructions. When confirming the detection of an adverse effect of the drug on the animal's body, veterinary specialists shall take samples in the required quantity for laboratory tests, develop a sampling report and send it to the State Institution "Belarusian State Veterinary Center" (220005, Minsk city, 19A Krasnaya str.) for confirmation of compliance with regulatory documents.

6 Full name of the manufacturer

6.1 Limited Liability Company "Stovek", the Republic of Belarus, 222660, Minsk region, Stolbtsy, 2 Zadvoryenskaya str.

The Instructions for use of the drug was developed by the employees of Stovek LLC (Piotukh A.S., Plomodjalov D.A.)

/Stamp:

Department of Veterinary and Food
Supervision of the Ministry of Agriculture and
Food of the Republic of Belarus
Council for Veterinary Drugs

APPROVED,

Chairman /signed/

Secretary /signed/

Expert /signed/

08.11.2022 minutes No. 123/