

INSTRUCTIONS for Use of the Veterinary Drug Ofloxum 10% OR

1. General Information

1.1 The veterinary drug Ofloxum 10% OR.

International Nonproprietary Name of the Active Pharmaceutical Substance: ofloxacin (ofloxacinum).

Dosage form: oral solution.

1.2 The veterinary drug Ofloxum 10% OR (hereinafter referred to as the drug) is a liquid ranging in color from colorless to yellow. A small amount of sediment may form, which disperses upon shaking.

1.3 Each 1.0 ml of the drug contains 100 mg of ofloxacin as the active ingredient and the following excipients: propylene glycol, benzyl alcohol, purified water.

1.4 The drug is packaged in polyethylene containers with screw caps of 100, 500, and 1000 ml.

1.5 The drug should be stored in the manufacturer's packaging (List B) in a place protected from direct sunlight at a temperature not exceeding 25°C. Keep out of reach of children.

1.6 Shelf life of the drug is 2 (two) years from the date of manufacture under the conditions of storage and transportation. Do not use after the expiration date. After the expiration date, the drug must be disposed of in accordance with legislation.

1.7 Dispensing conditions: over-the-counter, without a veterinary prescription.

2. Pharmacological Properties

2.1 Ofloxacin, the active ingredient of the drug, is a synthetic antibiotic from the second generation fluoroquinolone group. It is active against both Gram-negative and Gram-positive microorganisms, including *Escherichia coli*, *Salmonella spp.*, *Enterobacter spp.*, *Proteus spp.*, *Pseudomonas spp.*, *Haemophilus spp.*, *Staphylococcus spp.*, as well as chlamydia, mycoplasmas, and other microorganisms sensitive to ofloxacin.

2.2 The mechanism of action of ofloxacin is based on inhibiting the activity of the DNA gyrase enzyme (Type II topoisomerase), which affects the replication of DNA helices in the bacterial cell nucleus.

2.3 Ofloxacin is rapidly absorbed from the gastrointestinal tract and is completely distributed throughout the body. In organs and tissues, the concentration of ofloxacin exceeds the blood concentration by 2–3 times. The highest concentrations are found in the lungs, liver, kidneys, bones, and lymphatic system organs. The maximum concentration in blood is reached 0.5–1 hour after administration and is maintained for 4–6 hours, while the therapeutic concentration lasts for 24 hours.

2.4 Ofloxacin is excreted mainly via urine (about 75–90%), and in lactating animals—also with milk.

2.5 The drug belongs to low-hazard substances (hazard class 4 according to GOST 12.1.007-76).

3. Directions for Use

3.1 The drug is prescribed to young cattle, pigs, and poultry for the treatment of respiratory, gastrointestinal, genitourinary tract diseases, and other infections caused by microorganisms sensitive to ofloxacin.

3.2 The drug is administered orally with drinking water in the following doses:

- For calves and pigs: 0.5 ml per 10 kg of body weight for 3–5 days, administered individually or by group method;
- For broilers, turkeys, pullets, and parent stock: 50 ml per 100 liters of drinking water; in chronic cases – 100 ml per 100 liters of water (group method) or 0.5 ml per 10 kg of body weight (individual method) for 3–5 days. The medicated solution should be freshly prepared daily in an amount intended for consumption within one day. During the treatment period, animals should receive only

water containing the drug. When used at the recommended doses, the drug does not cause side effects or complications.

3.3 Simultaneous use of the drug with macrolides, cephalosporins, tetracyclines, theophylline, nonsteroidal anti-inflammatory drugs, and drugs containing magnesium, aluminum, or calcium cations is contraindicated.

3.4 The drug must not be used in poultry producing eggs for human consumption, adult ruminants with developed rumen digestion, pregnant and lactating females, animals with severe cartilage development disorders, or in cases of nervous system diseases accompanied by seizures.

3.5 In case of individual hypersensitivity to fluoroquinolones and appearance of side effects (refusal to eat, vomiting, edema, impaired coordination), discontinue the drug and provide symptomatic treatment.

3.6 Slaughter of cattle and pigs for meat is permitted not earlier than 14 days, and poultry—12 days after the last administration of the drug. Meat from animals and poultry slaughtered before the end of this period may be used for feeding carnivorous animals.

4. Precautionary Measures

4.1 When handling the drug, standard personal hygiene and safety measures must be observed. If the drug comes into contact with the skin or mucous membranes, rinse thoroughly with water.

5. Claims Procedure

5.1 In case of complications following the use of the drug, its administration should be discontinued, and the consumer must contact the State Veterinary Institution in their area. Veterinary specialists of this institution shall assess whether all instructions for the use of the drug were properly followed. If the adverse effect of the drug on the animal is confirmed, the veterinary specialists shall collect samples in the required quantity for laboratory testing – no fewer than 3 unopened packages of the drug from the batch that caused the complication. A sample collection report is then prepared and sent to the State Institution "Belarusian State Veterinary Center" for compliance verification with regulatory documentation (Minsk, 19A Krasnaya St., Tel.: +375 17 290 42 75).

6. Manufacturer Information

6.1 Production Cooperative "Biogel".

Legal address: Republic of Belarus, 220035, Minsk, 65 Timiryazeva St., office 313.

Manufacturing site address: Republic of Belarus, 222680, Minsk region, Stolbtsy district, Derevnoe village.

Produced by order of the Private Production and Trade Unitary Enterprise "Letyal", Republic of Belarus, 220075, Minsk, 1E Inzhenernaya St.

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