

## **INSTRUCTIONS**

### **for Use of the Veterinary Drug Letribafloxum**

#### **1. General Information**

1.1 The veterinary drug Letribafloxum.

International nonproprietary names: enrofloxacin, ribavirin, trimethoprim.

Dosage form: solution for intramuscular and subcutaneous administration.

1.2 The veterinary drug "Letribafloxum" (hereinafter referred to as the drug) is a clear solution ranging in color from colorless to yellow. Each 1.0 ml of the drug contains the following active substances: enrofloxacin – 55 mg, ribavirin – 25 mg, trimethoprim – 10 mg, and excipients: benzyl alcohol and water for injection.

1.3 The drug is supplied in glass vials of 50.0 ml and 100.0 ml.

1.4 Shelf life – two years from the date of manufacture. Keep out of reach of children.

1.5 Store with precautions in accordance with List B in a dry, dark place at a temperature from +5°C to +25°C. After opening and withdrawal of the first dose, the contents of the vial may be stored at a temperature from +2°C to +8°C and used within 24 days. Do not use after the expiration date.

#### **2. Pharmacological Properties**

2.1 Enrofloxacin, which is part of the drug, belongs to the group of fluoroquinolones. It has a broad spectrum of antibacterial action, inhibiting the growth and development of both gram-positive and gram-negative microorganisms, including *Escherichia coli*, *Haemophilus parasuis*, *Klebsiella spp.*, *Bordetella bronchiseptica*, *Clostridium spp.*, *Erysipelothrix rhusiopathiae*, *Pasteurella multocida*, *Mannheimia haemolytica*, *Corynebacterium spp.*, *Pseudomonas spp.*, *Campylobacter spp.*, *Bacteroides spp.*, as well as *Mycoplasma spp.* The mechanism of action of enrofloxacin lies in inhibiting the activity of the gyrase enzyme, which affects DNA replication in the nucleus of the bacterial cell.

2.2 Ribavirin is a broad-spectrum antiviral agent, active against DNA- and RNA-containing viruses, inhibits the synthesis of nucleic acids, and prevents viral replication.

2.3 Trimethoprim is a bacteriostatic antibiotic mainly used for the prevention and treatment of urinary tract diseases. It is active against certain gram-negative and gram-positive microorganisms. The mechanism of action is associated with inhibition of the enzyme dihydrofolate reductase in the process of tetrahydrofolic acid synthesis.

2.4 The drug is well and rapidly absorbed from the injection site and penetrates all organs and tissues of the body. Maximum concentration is reached within 1–2 hours after administration and is maintained for 6 hours; therapeutic concentration is sustained for 24 hours. The drug is excreted from the body in urine and bile.

#### **3. Directions for Use**

3.1 Letribafloxum is used to treat young pigs, cattle, and small ruminants for infections of mixed etiology affecting the respiratory system (bronchopneumonia, pneumonia, atrophic rhinitis), digestive system (gastroenteritis, enteritis, colitis), urogenital system (mastitis-metritis-agalactia syndrome, cystitis, pyelonephritis), septicemia, and other diseases caused by viruses and bacteria sensitive to the drug components.

3.2 The drug is administered once daily for 3–5 days:

- To piglets in the first 10 days of life: intramuscularly at a dose of 0.3–0.4 ml per animal;
  - To piglets older than 10 days: intramuscularly at a dose of 1.5 ml per 10 kg of body weight;
  - To calves, lambs, and kids: subcutaneously at a dose of 1.0 ml per 10 kg of body weight.
- The volume of the drug administered should not exceed 5.0 ml per injection site in large animals and 2.5 ml in small animals.

3.3 In rare cases, animals may experience temporary gastrointestinal disturbances. Prolonged use of the drug may lead to thrombocytopenia.

3.4 Do not use in lactating animals, during pregnancy, or in animals with cartilage development disorders or neurological conditions accompanied by seizures.

3.5 Do not administer the drug concurrently with amphenicols, macrolides, tetracycline, theophylline, or nonsteroidal anti-inflammatory drugs.

3.6 Slaughter of animals for meat is permitted no earlier than 14 days after the last administration of the drug. Meat from animals slaughtered before the specified period may be used to feed carnivorous animals.

#### **4. Precautionary Measures**

4.1 When working with the drug, follow personal hygiene and safety procedures.

#### **5. Claims Procedure**

5.1 In case of complications after use of the drug, its application should be discontinued, and the consumer should contact the State Veterinary Institution at their location. Veterinary specialists from the institution will verify adherence to all usage instructions. If the negative effect of the drug on the animal is confirmed, specialists will collect samples in the required quantity for laboratory testing, including at least 3 unopened packages from the batch that caused the complication, and send them along with a sampling report to the State Institution "Belarusian State Veterinary Center" for compliance confirmation to regulatory documents at the following address: 220005, Minsk, Krasnaya St. 19-A, Tel.: 290-42-75.

#### **6. Manufacturer Information**

6.1 Production Cooperative "Biogel", legal address: Republic of Belarus, 220035, Minsk, Timiryazeva St., 65, office 313.

Manufacturing site address: Republic of Belarus, 222685, Minsk region, Stolbtsy district, Nivnoye village.

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

The instructions for use of the drug were developed by the staff of PC "Biogel" (L.E. Yanshevskaya) and PE "Letyal" (A.N. Bezborodkin).