

## **INSTRUCTIONS** **for Use of the Veterinary Drug Letobaktan**

### **1. General Information**

1.1 The veterinary drug Letobaktan.

1.2 The veterinary medicinal product Letobaktan (hereinafter referred to as the product) is a sterile suspension ranging in color from white to cream. Layering is permissible during storage. Each 1.0 ml of the product contains 25 mg of cefquinome as the active ingredient, and excipients: sunflower oil, butanol, distilled water.

1.3 The product is packaged in 10.0, 50.0, and 100.0 ml glass vials for medicinal products, sealed with rubber stoppers and crimped with aluminum caps.

1.4 The product must be stored in the manufacturer's original packaging, according to List B, in a dry, dark place at temperatures between +2°C and +25°C. Keep out of reach of children.

1.5 Shelf life of the product under proper storage conditions is 2 (two) years from the date of manufacture. After opening the vial, the product must be used within 24 hours if the remainder is stored at a temperature between +3°C and +8°C. Do not use the product after the expiration date.

### **2. Pharmacological Properties**

2.1 Cefquinome sulfate, the active component of the product, is a 4th-generation cephalosporin with a broad-spectrum antibacterial effect against most gram-positive and gram-negative bacteria, including *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter spp.*, *Staphylococcus aureus*, *Streptococcus spp.*, *Clostridium spp.*, *Actinobacillus spp.*, *Citrobacter spp.*, *Klebsiella spp.*, *Pasteurella spp.*, *Proteus spp.*, *Salmonella spp.*, *Serratia marcescens*, *Haemophilus parasuis*, *Corynebacterium spp.*, *Fusobacterium necrophorum*, *Erysipelothrix rhusiopathiae*, and other microorganisms sensitive to cefquinome.

2.2 The product's mechanism of action involves inhibiting the synthesis of the bacterial cell wall. After parenteral administration, cefquinome enters the systemic circulation, reaching maximum serum concentration in cattle within 60–90 minutes, and in pigs within 15–60 minutes, maintaining therapeutic levels for 24 hours. Cefquinome binds to serum proteins at less than 5%.

2.3 Cefquinome sulfate is excreted relatively quickly, primarily unchanged via the urine (half-life in cattle is 2–2.5 hours, in pigs – 9 hours).

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

3.1 The product is used in cattle and pigs for the treatment of gastrointestinal and respiratory diseases caused by microorganisms sensitive to cefquinome.

3.2 Cattle: intramuscular injection at a dose of 2.0 ml per 50.0 kg of body weight.

- For pasteurellosis and foot diseases: once daily for 3–5 days;
- For mastitis: once daily for 2 days;
- For septicemia in calves: 2.0–4.0 ml per 50 kg body weight intramuscularly once daily for 3–5 days (depending on disease severity).

3.3 Pigs: intramuscular injection at a dose of 2.0–4.0 ml per 50 kg body weight.

- For respiratory diseases caused by *Pasteurella multocida*, *Haemophilus parasuis*, *Actinobacillus pleuropneumoniae*, *Streptococcus suis*, and other bacteria sensitive to cefquinome: once daily for 3 days;
- For metritis-mastitis-agalactia syndrome involving *E. coli*, *Staphylococcus spp.*, *Streptococcus spp.*, *Corynebacterium spp.*, and other cefquinome-sensitive bacteria: once daily for 2 days;
- For erysipelas and skin diseases in pigs: once daily at 4.0 ml per 50.0 kg of body weight for 3 days;

- For diseases in piglets caused by *Streptococcus* spp., *Staphylococcus* spp., etc.: once daily at 2.0–4.0 ml per 50.0 kg of body weight for 3–5 days (depending on severity).

3.4 Shake the vial thoroughly before use to obtain a uniform suspension.

3.5 Do not use in animals with hypersensitivity to cefquinome or other  $\beta$ -lactam antibiotics, or in combination with aminoglycosides.

3.6 No complications are generally observed when the product is used in accordance with this instruction. Some animals may exhibit a local reaction at the injection site in the form of swelling, which resolves spontaneously within 10–15 days. In the case of individual hypersensitivity and allergic reactions, antihistamines and symptomatic therapy should be administered.

3.7 Slaughter of cattle and pigs for meat is permitted no earlier than 8 days after the last administration of the product. Milk from dairy cows must not be used for food during treatment and for 5 days after the last administration. In the case of forced slaughter before the specified period, the meat may be used to feed carnivorous animals.

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

4.1 Standard personal hygiene and safety procedures must be followed when working with the product.

4.2 In case of contact with skin or mucous membranes, rinse thoroughly with water.

4.3 Do not reuse the product container for household purposes.

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

5.1 In case of complications after product use, discontinue administration and contact the state veterinary institution in your area. Veterinary professionals will verify adherence to the product usage instructions. If a negative effect on the animal is confirmed, samples (at least 3 unopened packages from the batch in question) will be taken for laboratory analysis, and a sampling report will be sent to the State Institution "Belarusian State Veterinary Center", Minsk, Krasnaya Street 19a, Tel.: 290-42-75, to verify compliance with regulatory standards.

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

6.1 Production Cooperative "Biogel", Republic of Belarus, 220035, Minsk, Timiryazeva St. 65, Office 313, manufactured on behalf of the Private Manufacturing and Trade Unitary Enterprise "Letyal", Republic of Belarus, 220005, Minsk, Inzhenernaya St. 1-E.

The instruction was developed by PC "Biogel" (L.E. Yanushevskaya) and PPTUE "Letyal" (A.N. Bezborodkin).