

## **INSTRUCTION**

### **for Use of the Veterinary Drug Ceftilet LC**

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

1.1 The veterinary drug Ceftilet LC.

International Nonproprietary Name of the active pharmaceutical substance: ceftiofur (ceftiofurum).

Dosage form: suspension for intramammary administration.

1.2 The veterinary drug Ceftilet LC (hereinafter referred to as the drug) is an oily suspension ranging in color from white to cream. One syringe-dispenser contains 125 mg of ceftiofur (in the form of ceftiofur hydrochloride) as the active ingredient and the following excipients: aluminum stearate, vegetable oil.

1.3 The drug is packaged in single-use polymer syringe-dispensers of 10 ml

1.4 The drug should be stored and transported in the manufacturer's packaging, protected from direct sunlight, at temperatures from 2°C to 25°C. Do not freeze. Keep out of reach of children.

1.5 Shelf life of the drug is two (2) years from the date of manufacture, provided storage and transportation conditions are met. Do not use after the expiration date. Upon expiration, the drug is disposed of in accordance with legal regulations.

1.6 Dispensing conditions: without a veterinary prescription.

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

2.1 The drug belongs to the group of cephalosporins.

2.2 Ceftiofur hydrochloride, the active ingredient in the drug, is a third-generation cephalosporin antibiotic with a broad spectrum of bactericidal activity against gram-positive (including *Staphylococcus spp.*, *Streptococcus spp.*, including  $\beta$ -lactamase-producing strains, *Arcanobacterium spp.*, *Fusobacterium necrophorum*) and gram-negative bacteria (including *Escherichia coli*, *Salmonella spp.*, *Campylobacter spp.*, *Shigella spp.*), and other pathogens sensitive to ceftiofur.

2.3 The bactericidal mechanism of action of ceftiofur consists in inhibiting the functional activity of bacterial transpeptidase enzymes involved in the binding of the main component of the bacterial cell wall – peptidoglycan – which leads to disruption of osmotic balance and destruction of the bacterial cell.

2.4 When administered intramammarily, ceftiofur is poorly absorbed, thereby ensuring high antibacterial concentrations of the drug in the udder. Ceftiofur and its metabolites are excreted from the animal's body mainly via the urine.

2.5 The drug is classified as low-hazardous (Hazard Class IV according to GOST 12.1.007-76).

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

3.1 The drug is used for the treatment of cows with mastitis of bacterial etiology during lactation.

3.2 The drug is administered to cows intramammarily, twice, with an interval of 24 hours, in a dose of 10 ml (contents of one syringe-dispenser) into the affected quarter of the udder. If necessary, therapy can be extended for no more than 8 days.

3.3 Before administration, milk from the affected quarter of the udder must be milked out; the teat should be disinfected externally. Then, the syringe-dispenser's cannula is carefully inserted into the teat canal and the contents slowly expelled. Then, the cannula is removed, the teat tip is pinched with fingers, and the teat is gently massaged from the bottom upward for 1–2 minutes to ensure better distribution of the drug. Shake the syringe-dispenser vigorously before use.

3.4 Do not use in animals with previously diagnosed hypersensitivity to ceftiofur or other beta-lactam antibiotics.

3.5 When used at the recommended doses and according to the instructions, no side effects or complications are observed. In case of allergic or other adverse reactions, discontinue the drug and administer antihistamines.

3.6 The use of the drug does not preclude the use of other medicinal products, except for those intended for intramammary administration.

3.7 Animals may be slaughtered for meat no earlier than 2 days after the last administration of the drug. Meat from animals slaughtered before the end of this period may be used to feed carnivorous animals.

3.8 Milk may be used for food purposes no earlier than 72 hours after the last administration of the drug. Milk obtained before the specified period from healthy quarters of the udder may be used after boiling for feeding animals. Milk from affected quarters must be decontaminated by boiling and discarded.

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

4.1 When working with the drug, standard personal hygiene practices and safety procedures must be followed.

4.2 Persons with hypersensitivity to the components of the drug should avoid direct contact with it.

4.3 Empty packaging must not be used for household purposes; it should be disposed of with household waste.

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

5.1 In the event of complications following administration of the drug, its use should be discontinued, and the consumer should contact the state veterinary institution in their region. Veterinary specialists of the institution shall examine whether all instructions for drug administration were followed. If the drug's adverse effect on the animal is confirmed, specialists shall collect samples in the required quantity for laboratory testing – at least 3 syringe-dispensers from the batch that caused the complication – and draw up a sample collection report to be sent to the state institution "Belarusian State Veterinary Center" for compliance verification with regulatory documents, at the address: Minsk, 220005, 19A Krasnaya St., Tel.: 8(017)290-42-75.

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

6.1 Production Cooperative "Biogel".

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

Production site address: Republic of Belarus, 222685, Minsk Region, Stolbtsy District, village Nivnoye.

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

The instructions for the use of the drug were developed by employees of PC "Biogel" (L.E. Yanushevskaya) and Private Enterprise "Letyal" (A.N. Bezborodkin).