

INSTRUCTIONS

for Use of the Veterinary Drug Ceftilet DC

1. General Information

1.1 The veterinary drug Ceftilet DC.

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

Pharmaceutical form: suspension for intramammary administration.

1.2 The veterinary medicinal product Ceftilet DC (hereinafter referred to as the product) is an oily suspension ranging in color from white to cream; layering during storage is acceptable. Each 10 ml (one syringe-dispenser) contains 500 mg of ceftiofur (in the form of ceftiofur hydrochloride) as the active ingredient and excipients: aluminum stearate, vegetable oil.

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

1.4 The product is stored and transported in the manufacturer's packaging in a place protected from direct sunlight at temperatures between 2°C and 25°C. Do not freeze. Keep out of the reach of children.

1.5 Shelf life of the product is 2 (two) years from the date of manufacture, provided storage and transportation conditions are met. Do not use after the expiration date. After the expiration date, the product is to be disposed of in accordance with legislation.

1.6 Dispensing conditions: without veterinary prescription.

2. Pharmacological Properties

2.1 The product belongs to the cephalosporin group.

2.2 Ceftiofur hydrochloride, included in the product, is a third-generation cephalosporin antibiotic with a broad spectrum of bactericidal activity against Gram-positive (including *Staphylococcus spp.*, *Streptococcus spp.*, including β -lactamase-producing strains, *Arcanobacterium spp.*, *Fusobacterium necrophorum*) and Gram-negative bacteria (including *Escherichia coli*, *Salmonella spp.*, *Campylobacter spp.*, *Shigella spp.*), as well as other pathogens sensitive to ceftiofur.

2.3 The bactericidal mechanism of action of ceftiofur is based on the inhibition of bacterial enzyme transpeptidase activity, which is involved in binding the main component of the microbial cell wall – peptidoglycan – leading to osmotic imbalance and destruction of the bacterial cell.

2.4 Upon intramammary administration, ceftiofur is poorly absorbed, thereby ensuring high antibacterial concentrations of the product in the udder. After administration during the dry period, a high concentration of the active substance remains in the mammary secretion for 19–28 days.

2.5 The product is classified as low hazard (hazard class IV according to GOST 12.1.007-76).

3. Directions for Use

3.1 The product is used for the treatment of cows with mastitis of bacterial origin during the dry period, but no later than 30 days before the expected calving date.

3.2 Not intended for use during lactation. Permitted for use immediately after the end of lactation before the transition to the dry period, but no later than 30 days before the expected calving.

3.3 The product is administered to cows once, intramammarily, immediately after the end of lactation, in a dose of 10 ml (contents of one syringe-dispenser) into the affected quarter of the udder. Prior to administration, the milk must be completely milked from the affected quarter, and the teat must be disinfected externally. Then, the cannula of the syringe-dispenser is gently inserted into the teat canal and the contents are slowly and carefully expressed. After that, the cannula is removed, the tip of the teat is pinched with fingers, and the teat is gently massaged from the bottom upward for 1–2 minutes to ensure even distribution of the product. Shake the syringe-dispenser vigorously before use.

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

3.5 When used in the recommended doses and according to the instructions, no adverse reactions or complications are observed. In the event of allergic or other adverse reactions, the product should be discontinued and antihistamines prescribed.

3.6 The use of the product does not preclude the use of other agents, except for those intended for intramammary administration.

3.7 Slaughter of animals for meat is allowed no earlier than 16 days after the last use of the product. 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 30 days after the last use of the product. Milk obtained before the expiration of the established period from healthy quarters may be used after boiling for animal feed. Milk from infected quarters must be disinfected by boiling and disposed of.

4. Precautionary Measures

4.1 When working with the product, personal hygiene measures and safety rules must be observed.

4.2 Individuals with hypersensitivity to the components of the medicinal product should avoid direct contact with the product.

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

5. Claims Procedure

5.1 In case of complications after the use of the product, its use is discontinued, and the consumer contacts the state veterinary institution in their region. Veterinary specialists of this institution will verify compliance with all application rules according to the instructions. If the negative impact of the product on the animal's body is confirmed, samples are taken in the required quantity for laboratory testing (at least 3 unused syringe-dispensers from the batch that caused the complication), a sampling report is drawn up, and the samples are sent to the State Institution "Belarusian State Veterinary Center" for compliance verification with regulatory documents: Minsk, 220005, 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.

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

Manufactured on request of the Private Manufacturing and Trading Unitary Enterprise "Letyal", Republic of Belarus, 220075, Minsk, 1E Inzhenernaya St.

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