APPROVED
Veterinary Medicines Council
Minutes No 117 of October 28, 2021

Instructions for Use of the veterinary product Ceftidject LA-TRV

1. General Product Information

1.1 Ceftidject LA-TRV (Ceftidjectum LA-TRV).

International nonproprietary name of the active pharmaceutical ingredient: ceftiofur.

1.2 The product is a white to yellow suspension. The layering occurs during storage which disappears on shaking. Dosage form: suspension for intramuscular and subcutaneous injection.

1.3 Each ml of the veterinary product contains 100 mg of ceftiofur (as crystalline free ceftiofuric acid), excipients (methylparaben, propylparaben, butylhydroxytoluene, vegetable oil) and base (medium chain triglycerides).

1.4 The veterinary product is packed in glass vials of 10; 20; 30; 50; 100; 200 and 400 ml.

1.5 The veterinary product is stored in the manufacturer's package as per list B, in a dry, dark place at a temperature of plus 5 ° C to plus 25 ° C.

1.6 Shelf life is two years from the date of manufacture, subject to the conditions of storage and transportation. Once opened the package is stored no more than 10 days. Do not use the veterinary product after expiry date. Dispose of unused product in accordance with legal requirements.

2. Pharmacological Properties

2.1 Ceftiofur is a third-generation, broad-spectrum cephalosporin antibiotic with bactericidal action against Gram-negative (*Escherichia coli, Klebsiella spp., Pasteurella spp., Haemophilus spp., Actinobacillus pleuropneumoniae., Bacteroides spp., Citrobacter spp., Enterobacter spp., Salmonella spp.,*) and Gram-positive bacteria (*Bacillus spp., Streptococcus spp., Staphylococcus spp., Actinomyces pyogenes*), including lactamase-producing strains as well as some strains of anaerobes (*Proteus spp., Fusobacterium necrophorum*).

2.2 The veterinary product inhibits the enzyme transpeptidase, disrupting the synthesis of peptidoglucan, a mucopeptide of the cell membrane, leading to disruption of its growth and lysis of bacteria.

2.3 After parenteral administration in therapeutic dose maximum concentration of active substance is achieved in blood plasma of cattle after 12 hours, and in pigs - after 22 hours and maintained at therapeutic level for at least 7 days.

2.4 In the body ceftiofur is rapidly metabolised to form desfuroylceftiofur, which has activity equivalent to ceftiofur against bacteria. This active metabolite binds reversibly to plasma proteins and accumulates at the site of infection, and its activity is not reduced in the presence of necrotic tissue. The elimination of the veterinary product from animals occurs mainly with urine (about 70%) and faeces (12-15%). In case of liver and kidney dysfunction, the elimination period may be prolonged.

3. Application Procedure

3. 1 The veterinary product is used for treatment of cattle and small ruminants, poultry and pigs with infectious diseases of bacterial etiology of respiratory system, gastrointestinal tract and urogenital system; in sepsis, peritonitis, pyelonephritis, polyarthritis, polyserositis, wounds, postnatal infections, mastitis, necrobacillosis and other caused by microorganisms sensitive to ceftiofur.

3.2 Before use, the bottle should be shaken thoroughly until a homogeneous suspension is obtained. In cold seasons, the veterinary product should be heated in a water bath to the body temperature of an animal.

3.3 In cattle and small ruminants the product is administered once, subcutaneously in dose of 1 ml per 15 kg of animal body weight (equivalent to 6.6 mg ceftiofur per 1 kg). It is recommended to administer not more than 20 ml at a single injection site.

3.4 In poultry the preparation is administered singly, intramuscularly in dose 0.05-0.2 ml per 10 kg body weight (1-4 mg ceftiofur per 1 kg body weight).

3.5 For pigs the preparation is administered once intramuscularly in dose of 1 ml per 20 kg of animal body weight (equivalent of 5 mg ceftiofur per 1 kg). It is recommended to administer not more than 4 ml at a single injection site.

3.6 In recommended doses the drug does not cause adverse effects. In some cases, swelling may form at the injection site and disappear spontaneously.

3.7 The product is prohibited for treatment of animals with hypersensitivity to cephalosporin antibiotics. In case of allergic reactions the drug shall be discontinued and antihistamines and symptomatic treatment shall be started.

The product should not be used in poultry whose eggs are used for human consumption.

3.8 The drug should not be mixed in the same syringe with other drugs. Co-administration with bacteriostatic antibiotics reduces the antimicrobial activity of the drug.

3.9 Slaughter for meat of poultry, cattle and small ruminants shall be carried out not earlier than 20 days, pigs - 71 days after the last drug administration. Meat of animals and poultry slaughtered before expiry of specified period may be used to feed carnivorous animals. Milk for human consumption should not be used earlier than 24 hours after the last drug administration. Before expiry of specified period the milk shall be fed to animals after heat treatment.

4 Personal Precautions

4.1 Generally accepted personal hygiene and safety precautions should be observed when handling the product.

5 Claiming Procedure

5.1 In the event of complications following the use of the product, its use shall be discontinued and the user shall contact the State Veterinary Institution where the product is located. The veterinary staff of the institution shall investigate compliance with all rules for the use of the preparation in accordance with the instructions. In case of confirmation of the adverse effect on the animal's organism veterinary specialists take the samples in the required quantity for laboratory tests, draw up a sampling certificate and send it to the State Enterprise "Belarusian State Veterinary Centre" (220005, Minsk, Krasnaya Street 19A) for confirmation of compliance with the regulations.

6 Full name of the manufacturer

6.1 Stovek, Limited Liability Company, Republic of Belarus, 222660, Minsk Region, Stolbtsy, Zadvoryenskaya St., 2

Instructions for use are developed by employees of Stovek, LLC (Piotukh A.S., Plomodyalov D.A.).

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Control of the Ministry of Agriculture and
Food of the Republic of Belarus
Veterinary Medicinal Product Council
Approved

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