APPROVED
Veterinary Medicines Council
Minutes No 119 of February 24, 2022

Instructions for Use
of the veterinary product
Lexodgect

1. General Product Information

1.1 Lexodgect (Lexodgectum).

International nonproprietary name of the active pharmaceutical ingredient: Levofloxacin.

1.2 The veterinary product is a light yellow to dark yellow transparent liquid without mechanical impurities.

Dosage form: solution for intramuscular injection.

1.3 Each ml of the veterinary product contains 150 mg of levofloxacin, excipients (hydrochloric acid, benzyl alcohol) and solvent (water for injection).

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 7 days. Do not use the veterinary product after expiry date. Dispose of unused product in accordance with legal requirements.

2. Pharmacological Properties

2.1 Levofloxacin, the veterinary product's component, is a synthetic chemotherapeutic antibiotic from the fluoroquinol group.

The product has a broad spectrum of antimicrobial action against aerobic gram-positive micro-organisms (*Enterococcus spp., Listeria monocytogenes, Staphylococcus spp.* (including *Staphylococcus aureus*), *Streptococcus spp.*), aerobic gram-negative micro-organisms (*Campylobacter spp., Enterobacter spp., Escherichia coli, Haemophilus spp., Klebsiella spp., Pasteurella spp., Mannheimia haemolytica, Proteus spp., Pseudomonas spp., Salmonella spp.*), anaerobic micro-organisms (*Clostridium perfringens, Fusobacterium necrophorum*), as well as *Bordetella spp., Chlamydia spp., Mycobacterium spp., Mycoplasma spp., Ricketsia spp*. Micro-organisms do not develop resistance to the veterinary product after long-term use.

The product is effective against pathogens resistant to tetracyclines, aminoglycosides, macrolides, chloramphenicol, sulphonamides and trimethoprim.

2.2 Mechanism of action is associated with DNA-gyrase (topoisomerase II) and topoisomerase IV blockade, disruption of superspiralization and deoxyribonucleic acid gap cross-linking, inhibition of deoxyribonucleic acid synthesis, deep metabolic changes in cytoplasm, cell wall and membranes.

2.3 The product is rapidly and almost completely absorbed after parenteral administration. Bioavailability of levofloxacin is 99%, C_{max} is 2 hours after administration, elimination half-life is 7 hours. It penetrates well into organs and tissues: lungs, bronchial mucosa, sputum, urogenital organs, polymorphonuclear leukocytes, alveolar macrophages. It is mainly excreted by the kidneys by glomerular filtration or tubular secretion. Levofloxacin is mainly excreted unchanged in the urine within 48 hours. In lactating animals it is also excreted with milk. Minor amounts are detected in the faeces over a period of 72 hours. If liver and kidney function is impaired, the elimination period may be prolonged.

3. Application Procedure

3. 1 The veterinary product is used for treatment of pigs, cattle and small ruminants against bacterial infections of respiratory, digestive and urogenital systems, septicemia, colibacillosis, salmonellosis,

pasteurellosis, pseudomonosis, mycoplasmosis, haemophilia, bordetellosis, MMA syndrome (mastitis-metritis-agalactia) and atrophic rhinitis in pigs, mixed and secondary bacterial infections as well as other infectious diseases of bacterial etiology where pathogens are sensitive to levofloxacin.

3.2 The veterinary product is administered intramuscularly once a day for 3-5 days in the following doses:

- cattle, pigs - 1.0 ml per 30 kg of animal weight (5.0 mg of levofloxacin per 1 kg of animal body weight).

3.3 In case of overdose the animal may show loss of appetite, depression, vomiting, and diarrhea. There is no specific antidote, symptomatic treatment shall be carried out.

In case of allergic reactions (seizures, tremor, vomiting, hemolytic anemia), the veterinary product shall be cancelled and antihistamines and calcium preparations shall be used.

3.4 The veterinary product should not be used concomitant with tetracyclines, macrolides and amphenicols because of reduced antimicrobial activity of the veterinary product. Theophylline and/or non-steroidal anti-inflammatory veterinary products should not be used concomitantly with this veterinary product.

3.5 Individual hypersensitivity to components of the preparation, expressed liver and kidney dysfunction, significant cartilage development disorders, lesions of nervous system accompanied by convulsions are contraindications to its administration.

3.6 Slaughter for meat of pigs, cattle and small ruminants shall be carried out not earlier than 9 days after the last veterinary product administration. Meat of animals slaughtered before expiry of specified period may be used to feed fur animals.

Milk may be used for food purposes not earlier than 96 hours after the last veterinary product administration. Milk obtained before the expiry of the specified period may be used to feed 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
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