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

Instructions for Use
of the veterinary product
Lexol aqua

1. General Product Information

1.1 Lexol aqua (Lexolum aqua).

International nonproprietary name of the active pharmaceutical ingredient: Levofloxacin.

1.2 The veterinary product is a light yellow to dark yellow liquid. Slight precipitation during storage is allowed.

Dosage form: oral solution

1.3 Each ml of the veterinary product contains 150 mg of levofloxacin (as levofloxacin hemihydrate), excipients (hydrochloric acid, benzyl alcohol), solvent (purified water).

1.4 The veterinary product is available in polymeric package of 100.0; 500.0 ml and 1.0; 3.0; 5.0; 10.0; 15.0; 20.0; 25.0 L.

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., 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. Levofloxacin 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. If liver and kidney function is impaired, the elimination period may be prolonged.

2.4 The preparation is classified as a low-hazard substance (Hazard Class 4 according to GOST 12.1.007-76).

3. Application Procedure

3. 1 The veterinary product is used for treatment of pigs and farm poultry in colibacillosis, salmonellosis, pasteurellosis, pseudomoniasis, mycoplasmosis, haemophylosis, bordetellosis, MMA syndrome (mastitis-metritis-agalactia), infectious atrophic rhinitis in pigs as well as in other respiratory, digestive and urogenital system diseases, whose pathogens are sensitive to levofloxacin.

3.2 The veterinary product is administered orally for 3-5 days in the following dosages:

- pigs - individually 0.5 ml per 10 kg body weight of animal with a small amount of feed or water. In groups - 0.35-0.5 L of veterinary product per 1 ton of water for watering;

- in poultry (broiler chickens, young laying hens, parent stock, fattening turkeys) - 0.5 ml per 10 kg of poultry weight (7.5 mg of levofloxacin per 1 kg of poultry weight) or 0.35-0.5 ml of preparation per 1 ton of drinking water.

In case of salmonellosis and in severe cases of pigs the dose of the veterinary product is doubled. During treatment animals and poultry, in case of group method of application, shall receive only water containing the veterinary product, which shall be the only source of drinking. The prepared veterinary product solution should be used within 24 hours.

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 The veterinary product should not be used in poultry whose eggs are used for human consumption as well as in young laying hens whose eggs will be used for human consumption less than 10 days before the beginning of oviposition due to accumulation of levofloxacin in eggs. Administration of the veterinary product in gestating and lactating sows is prohibited.

3.7 Slaughter of animals for meat shall be allowed not earlier than 9 days, poultry not earlier than 7 days after the last drug administration. In case of compulsory slaughter of animals before the specified period, the meat shall be used to feed carnivores.

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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24.02.2022 Minutes No. 119