APPROVED
Council on veterinary drugs
Protocol №122, September 5th, 2022

Instruction
For usage of «Moxidgect LA-TRV» veterinary drug

1 General information

1.1 Moxidgect LA-TRV.

International non-proprietary name of the active pharmaceutical substance: moxifloxacin.

1.2 The drug is a light-yellow or dark-yellow liquid, without mechanical inclusions. Dosage form: solution for intramuscular injection.

1.3 1 milliliter of the drug contains 109 milligrams of moxifloxacin hydrochloride which is equivalent to 100 milligrams of moxifloxacin, excipients (L-arginine, butyl alcohol) and a solvent (water for injection).

1.4 The drug is packed into 10-, 20-, 30-, 50-, 100-, 200- and 400-milliliter glass vials.

1.5 The drug is stored in manufacturer's package according to the B-list in dry, protected from the sun place at temperature of 5°C up to 25°C above zero. Keep out of the reach of children.

1.6 Shelf life – 24 months from the date of production under storage and transportation conditions. After first opening of the pack – no longer than 7 days subject to the rules of asepsis. Do not use after expiry date. Unused drug is to be utilized according to legislation requirements.

2 Pharmacological features

2.1 The drug has a prolonged antimicrobial effect against a wide range of gram-positive and gram-negative microorganisms, anaerobic, acid-resistant and atypical bacteria, as well as bacterial strains resistant to beta-lactams and macrolides.

It is active against gram-negative (Escherichia coli, Klebsiella spp., Salmonella spp., Proteus spp., Campylobacter spp., Pseudomonas aeruginosa, Bordetella spp., Pasteurella spp., Haemophilus spp. (including both β-lactamase producing and non- β-lactamase producing strains), Actinobacillus spp., Moraxella spp., Enterobacter spp.), gram-positive bacteria (Staphylococcus epidermidis, Staphylococcus aureus (including β-lactamase producing ones), Streptococcus pneumoniae (including those resistant to penicillin and macrolides), Streptococcus pyogenes (A group), Streptococcus agalactiae, Streptococcus dysgalactiae, Corynebacterium spp.), anaerobic microorganisms: Clostridium spp., Bacteroides spp., Fusobacterium spp.), as well as Mycoplasma spp., Chlamydia spp., Leptospira spp.

Resistance to moxifloxacin develops slowly. Cross-resistance between moxifloxacin and other classes of antimicrobials is unknown.

2.2 Moxifloxacin – is a synthetic chemotherapeutic antibiotic belonging to the IV generation fluoroquinol group which has a pronounced post-antibiotic effect.

The mechanism of bactericidal action is due to the inhibition of enzymes (topoisomerases II (DNA gyrase) and IV) that leads to disruption of replication, repair and transcription of microbial DNA biosynthesis' processes and, as a result, the death of microbial cells.

The minimal bactericidal concentrations of moxifloxacin are comparable to its minimal inhibitory concentrations.

2.3 During parenteral administration the drug is well and quicky absorbed from the injection site and distributed throughout the body. High concentrations of moxifloxacin, exceeding those in plasma, are created in the lung tissue (including those in the epithelial fluid, alveolar macrophages), in the nasal sinuses (maxillary and ethmoid sinuses), in nasal polyps, foci of inflammation (in the contents of blisters with skin lesions), in the tissues of the abdominal organs, peritoneal fluid, as well as in the tissues of the genitourinary system. In the interstitial fluid and in saliva, moxifloxacin is determined in free, non-protein-bound form at a higher concentration rate than in plasma. Serum protein binding is made up to approximately 30-50% and does not depend on the concentration of the substance.

Moxifloxacin is subjected to biotransformation of the 2nd phase and is excreted from the body with urine and feces, both in unchanged and inactive sulfo compounds (M1) and glucuronides (M2) forms, as well as with milk in case of lactating animals. An increase in the elimination period is possible if liver and kidney functions are impaired.

3 Order of application

3.1 The drug is used for treatment of pigs, cattle with bacterial infections of the respiratory, digestive,

genitourinary systems, soft tissues septicemia, mastitis, colibacillosis, salmonellosis, pasteurellosis, pseudomonosis, mycoplasmosis, chlamydia, hemophilia, bordetellosis, MMA syndrome (mastitis-metritis-agalactia) and atrophic rhinitis of pigs, as well as other infectious diseases of bacterial etiology the pathogens of which are sensitive to moxifloxacin.

3.2 The drug is injected once intramuscularly in the following doses:

- pigs - 1 milliliter per 10 kilograms of animal's body mass, but not more than 10 milliliters into one injection site;
- cattle - 1 milliliter per 10 kilograms of animal's body mass, but not more than 20 milliliters into one injection site. If it is required, the injection of the drug is repeated after 48 hours.

3.3 It is possible that redness may appear at the injection site (primarily in pigs' case) which disappears on its own in a few days. Some animals may experience short-term dysfunction of the gastrointestinal tract (vomiting, diarrhea), as well as convulsions and tremor after the application. In this case, the usage of the drug is stopped and symptomatic treatment is carried out.

If allergic reactions occur (rash, itching, urticaria, anaphylactic shock), the usage of drug is cancelled and antihistamines and calcium medicine is used.

3 In case of overdose of the drug a decrease in animal's appetite, as well as depression, vomit and diarrhea may be observed. There is no specific antidote, symptomatic treatment is carried out.

3.4 Individual sensitivity of the animal to the components of the drug, severe violations of the liver and kidneys, significant cartilage tissue development disorder, damage to the nervous system accompanied by convulsions serve as contraindications for use of the drug.

3.5 The drug should not be used in conjunction with tetracyclines, macrolides and amphenicols due to decrease in the antimicrobial activity of the drug. It is not recommended to use it simultaneously with drugs containing theophylline and/or non-steroidal anti-inflammatory drugs.

3.6 The drug is used on pregnant and lactating animals if the benefits of its use outweigh the potential risk.

3.7 Slaughter for meat of cattle and pigs is allowed no earlier than 28 days after the last use of the drug. In case of forced slaughter of animals earlier than the aforementioned period, the meat is used as feed for carnivorous animals.

Milk for human consumption should be used no earlier than 7 days after the last use of the drug. Milk is fed to unproductive animals after boiling until the expiration of the specified period.

4 Prevention measures

4.1 In the process of work with the drug general rules of personal hygiene and safety measures should be followed.

5 Order of claim submission

5.1 In case of complications after the use of the drug, its use is stopped and the consumer contacts the State Veterinary Institution stationed to the territory that he is located in. Veterinary specialists of this institution are studying compliance with all the rules for the use of the drug in accordance with the instructions. If the negative effect of the drug on an animal body is confirmed, veterinary specialists take samples in the required quantity for laboratory testing, with a sampling report drawn up and sent to the State Institution "Belarussian State Veterinary Center" (The Republic of Belarus, 220005, Minsk, Krasnaya str., 19 A) for confirmation of compliance with regulatory documents.

6 Full name of manufacturer

6.1 Stovek LLC, The Republic of Belarus, 222660, Minsk region, Stolbtsy, Zadvorienskaya str., 2.

The instruction for usage of the drug is developed by employees of Stovek LLC (A.S. Piotukh, D.A. Plomodialov).