INSTRUCTIONS
for the use of the veterinary medicinal product Drotulket

1. General Information

1.1 The veterinary drug DrotulKet.

International non-proprietary names: Tulathromycin, Ketoprofen.

Dosage form: Solution for subcutaneous and intramuscular injection.

1.2 The veterinary product DrotulKet (hereinafter referred to as "the product") is a clear solution ranging in color from colorless to yellow or yellow-green.

1.3 Each 1.0 ml of the product contains 100 mg of tulathromycin and 120 mg of ketoprofen as active ingredients, and excipients: propylene glycol, sodium hydroxide, citric acid, hydrochloric acid, and purified water.

1.4 The product is supplied in 50 ml and 100 ml clear glass vials.

1.5 Store the product in the manufacturer's packaging, protected from direct sunlight, at temperatures between +2 °C and +25 °C. Do not freeze. After first opening and dose withdrawal, store the remaining product at +2 °C to +8 °C and use within 24 days. Keep out of reach of children.

1.6 Shelf life is 2 (two) years from the date of manufacture, provided proper storage and transportation conditions are observed. Do not use after the expiration date. Unused product must be disposed of in accordance with legal requirements.

1.7 Dispensing conditions: over-the-counter (no veterinary prescription required).

2. Pharmacological Properties

2.1 Tulathromycin, a component of the product, is a semi-synthetic antibiotic of the triamilide subclass of macrolides. It has a broad-spectrum bacteriostatic effect against Gram-positive (e.g., *Streptococcus spp.*, *Staphylococcus spp.*, including beta-lactamase producing strains) and Gram-negative bacteria (e.g., *Mannheimia haemolytica*, *Pasteurella multocida*, *Haemophilus parasuis*, *Actinobacillus spp.*), as well as mycoplasmas causing respiratory diseases in cattle and pigs. Ketoprofen is a nonsteroidal anti-inflammatory drug (NSAID) with anti-inflammatory, analgesic, and antipyretic properties.

2.2 Tulathromycin acts by binding to the 50S ribosomal subunit, inhibiting peptide chain translocation and elongation, thereby disrupting microbial protein synthesis. It also enhances non-specific immune defense and accumulates in phagocytes at concentrations significantly higher than in plasma, helping destroy intracellular pathogens. Ketoprofen works by inhibiting bradykinin, which stimulates pain receptors, thereby reducing pain. It also affects the central nervous system to suppress pain perception.

2.3 After subcutaneous or intramuscular injection, tulathromycin is rapidly absorbed, reaching peak plasma concentration within 30 minutes and is slowly eliminated. It accumulates in neutrophils and alveolar macrophages, resulting in high concentrations in lung tissue. The half-life is about 90 hours, with highest levels found in lungs, liver, and kidneys. Ketoprofen is also rapidly absorbed after parenteral administration, reaches effective concentration in 20–30 minutes, and lasts for 24 hours. More than 98% binds to plasma proteins and accumulates in inflamed tissues. Its bioavailability ranges from 85% to 100%.

2.4 Both tulathromycin and ketoprofen are primarily excreted via the kidneys in urine.

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 administered to cattle and pigs for respiratory diseases caused by pathogens sensitive to tulathromycin, including conditions accompanied by fever.

3.2 Before use, the product should be warmed in a water bath to +35 °C.

3.3 Dosage and administration:

- Cattle: Administer once subcutaneously at a dose of 1.0 ml per 40 kg body weight (2.5 mg tulathromycin and 3 mg ketoprofen per 1 kg). For animals over 300 kg, divide the dose so that no more than 7.5 ml is injected at one site.

- Pigs: Administer once intramuscularly in the neck at a dose of 1.0 ml per 40 kg body weight (2.5 mg tulathromycin and 3 mg ketoprofen per 1 kg). For pigs over 80 kg, divide the dose so that no more than 2 ml is injected at one site.

3.4 Subcutaneous injection may cause temporary pain and local inflammation, usually resolving in a few days, but may persist for up to 30 days.

3.5 At recommended doses, no side effects are observed except in cases of individual hypersensitivity to the components. If allergic reactions occur, discontinue use and administer antihistamines and symptomatic treatment.

3.6 Do not use concurrently with other macrolides or lincosamides. Contraindicated in animals with gastrointestinal ulcers, or liver, kidney, or heart diseases.

3.7 Do not administer to cows producing milk for human consumption or to pregnant heifers within 2 months before expected calving if the milk is intended for human use.

3.8 Withdrawal period:

- Cattle: 49 days after last administration.
- Pigs: 33 days after last administration.

Meat from animals slaughtered before the end of the withdrawal period may be used for feeding carnivorous animals only.

4. Precautionary Measures

4.1 When handling the product, observe personal hygiene and safety regulations.

5. Claims Procedure

5.1 In case of adverse reactions after using the product, discontinue use and contact the state veterinary institution in your region. Veterinary professionals will verify compliance with usage instructions. If the product is found to have adverse effects or is visually non-compliant, samples (at least 3 units from the batch) will be taken and sent to the "Belarusian State Veterinary Center" (220005, Minsk, Krasnaya Street 19A, Tel.: +375 17 290-42-75) for laboratory testing and verification of compliance with regulatory standards.

6. Manufacturer Information

6.1 Production Cooperative "Biogel"

Legal address: Republic of Belarus, 220035 Minsk, Timiryazeva Street 65, office 313.

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

Manufactured by order of Private Production and Trade Unitary Enterprise "Letyal", Republic of Belarus, 220075 Minsk, Inzhenernaya Street 1E.

The instruction was developed by employees of PC "Biogel" (L.E. Yanushevskaya) and PE "Letyal" (A.N. Bezborodkin).