

INSTRUCTIONS

for Use of the Veterinary Drug Drotul-plus

1. General Information

- 1.1 The veterinary drug Drotul-plus.
- 1.2 The preparation is a clear liquid ranging in color from colorless to light yellow.
- 1.3 Each 1.0 ml of the preparation contains 100 mg of tulathromycin and excipients: propylene glycol, distilled water.
- 1.4 The product is packaged in glass vials of 10.0, 50.0, and 100.0 ml.
- 1.5 Store the product in the manufacturer's packaging, in a dry, light-protected place, at temperatures between +5°C and +25°C. Keep out of reach of children.
- 1.6 Shelf life is two years from the date of manufacture if storage conditions are met. After opening and withdrawing the first dose, the contents of the vial may be stored at +3°C to +8°C for up to 24 hours. Do not use after the expiration date.

2. Pharmacological Properties

2.1 Tulathromycin, the active ingredient of the product, is a semi-synthetic antibiotic from the subclass of triamilides, belonging to the macrolide group. It has a broad spectrum of action and exhibits bacteriostatic activity against Gram-positive (*Streptococcus spp.*, *Staphylococcus spp.* including beta-lactamase-producing strains, *Corynebacterium pyogenes*, etc.) and Gram-negative bacteria (*Mannheimia haemolytica*, *Pasteurella multocida*, *Haemophilus somnus*), as well as *Mycoplasma hyopneumoniae*, *Mycoplasma bovis*, and *Actinobacillus pleuropneumoniae*, which cause respiratory diseases in cattle and pigs.

2.2 Tulathromycin binds to the 50S ribosomal subunit, inhibits peptide chain translocation, thereby disrupting the synthesis of microbial proteins. It also stimulates non-specific immune responses and, by accumulating in phagocytes at concentrations far exceeding those in blood plasma, destroys intracellular pathogens.

2.3 In cattle and pigs, tulathromycin is rapidly absorbed from the injection site, reaching peak plasma concentrations within 30 minutes, and is eliminated slowly. It accumulates in neutrophils and alveolar macrophages, resulting in high drug concentrations in lung tissue. The half-life of tulathromycin is approximately 90 hours. The drug is excreted unchanged via the kidneys, with the highest concentrations found in the lungs, liver, and kidneys.

3. Directions for Use

3.1 The product is used to treat cattle and pigs with pneumonia, bronchopneumonia, and other bacterial respiratory infections caused by organisms sensitive to tulathromycin.

3.2 Dosage:

- Cattle: Administered once subcutaneously at a dose of 1.0 ml per 40 kg of body weight (2.5 mg of tulathromycin per 1 kg of body weight). For animals over 300 kg, divide the dose so that no more than 7.5 ml is injected at a single site.
- Pigs: Administered once intramuscularly into the neck at a dose of 1.0 ml per 40 kg of body weight (2.5 mg of tulathromycin per 1 kg of body weight). For pigs over 80 kg, divide the dose so that no more than 2 ml is injected at a single site.

3.3 At low ambient temperatures, warm the product to +30°C in a water bath before use. Only dry syringes and needles should be used.

3.4 Do not mix the product with other drugs in the same syringe. Do not administer concurrently with other macrolides or lincosamides.

3.5 When used at recommended doses, the product is non-toxic. Pain or swelling may occur at the injection site, which usually resolves within a few days.

3.6 Contraindications: Individual hypersensitivity to macrolide antibiotics. Do not use in dairy cows producing milk for human consumption. Do not use in pregnant heifers or cows intended for

future milk production within two months of use. In cases of hypersensitivity, allergic reactions (dermatitis, itching, swelling) may occur. Treat with epinephrine and/or antihistamines (diphenhydramine, clemastine) and calcium preparations (calcium chloride or gluconate).

3.7 Slaughter of pigs for meat is permitted no earlier than 30 days after the last administration of the product. Meat from the injection site may be used no earlier than 68 days after the last administration. If animals are slaughtered earlier than 50 days after the last administration, the liver and kidneys must be discarded. After 50 days post-administration, the liver and kidneys may be used for human consumption without restrictions.

Slaughter of cattle for meat is permitted no earlier than 30 days after the last administration of the product. Meat from the injection site may be used for food purposes no earlier than 55 days after the last administration. If animals are slaughtered earlier than 68 days after the last administration, the liver and kidneys must be discarded. After 68 days post-administration, the liver and kidneys may be used for human consumption without restrictions. Meat from animals slaughtered before the specified withdrawal period may only be used to feed carnivorous animals.

4. Precautionary Measures

4.1 When handling the product, follow standard personal hygiene and safety procedures.

5. Claims Procedure

5.1 In the event of complications after use, stop administering the product and contact the manufacturer and the state veterinary institution in your area. Veterinary specialists will verify compliance with the instructions. If the product is suspected to cause adverse effects or does not match its description, samples will be collected and sent to the State Institution "Belarusian State Veterinary Center" (Minsk, Krasnaya St. 19a) for laboratory testing and compliance verification.

6. Manufacturer Information

6.1 Production Cooperative "Biogel", Republic of Belarus, 220035, Minsk, Timiryazeva St., 65, Offices 313, on behalf of Private Production and Trade Unitary Enterprise "Letyal" (Republic of Belarus, 220005, Minsk, Inzhenernaya St., 1-E).

The instruction was developed by PC "Biogel" (L.E. Yanushevskaya), and PPTUE "Letyal" (A.N. Bezborodkin).