INSTRUCTIONS
for Use of the Veterinary Drug Tylosalum 20%

1. General Information

1.1 The veterinary drug Tylosalum 20%

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

Dosage form: solution for intramuscular injection.

1.2 The veterinary drug Tylosalum 20% (hereinafter referred to as the drug) is a transparent yellow solution.

Each 1.0 ml of the drug contains 200 mg of tylosin tartrate as the active ingredient and the following excipients: propylene glycol, benzyl alcohol, and water for injection.

1.3. The drug is available in glass vials of 50 and 100 ml.

1.4 Store the drug with caution (List B), in a dry place protected from direct sunlight at a temperature between +2 °C and +25 °C. Keep out of reach of children.

1.5 Shelf life – 2 (two) years from the date of manufacture, provided the transportation and storage conditions are observed. After the vial is opened, use the contents within 24 days, storing at +2 °C to +8 °C. Do not use after the expiration date.

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

2. Pharmacological Properties

2.1. Tylosin is a macrolide antibiotic active against most gram-negative (Escherichia coli, Salmonella spp., Proteus spp., Pseudomonas spp., Bordetella bronchiseptica, Borrelia hyodysenteriae, Pasteurella multocida, Mannheimia haemolytica, Haemophilus parasuis, Actinobacillus pleuropneumoniae) and gram-positive (Staphylococcus spp., Streptococcus spp., Corynebacterium spp., Clostridium spp., Erysipelothrix insidiosa) bacteria, as well as mycoplasmas and chlamydiae.

The mechanism of action of tylosin is based on the inhibition of protein synthesis in the microbial cell by forming a complex with the 50S ribosomal subunit.

2.2. When administered intramuscularly, the drug is well absorbed from the injection site into the bloodstream and penetrates all organs and tissues of the animal. The highest concentrations of tylosin are found in the lungs, intestinal wall, liver, mammary glands, and kidneys. After a single administration, therapeutic concentrations of the antibiotic remain in the body for at least 20 hours.

The drug is excreted mainly via urine and bile, and in lactating cows, also in milk.

2.3. The drug is classified as low-hazard (hazard class IV according to GOST 12.1.007-76).

3. Directions for Use

3.1. The drug is used for pigs, cattle, and small ruminants in cases of respiratory diseases (rhinitis, laryngitis, bronchitis, pneumonia, and bronchopneumonia of bacterial origin), dysentery, swine erysipelas, infectious agalactia in sheep and goats, mastitis, endometritis, secondary infections on the background of viral diseases, and other bacterial pathologies caused by pathogens sensitive to tylosin.

3.2. The drug is administered intramuscularly once a day for 5–7 days in the following doses:

- Cattle: 0.25–0.5 ml per 10 kg of body weight, not exceeding 15.0 ml per injection site;
- Small ruminants: 0.4–0.5 ml per 10 kg of body weight, not exceeding 8.0 ml per injection site;
- Pigs: 0.5–0.6 ml per 10 kg of body weight, not exceeding 10.0 ml per injection site.

3.3. In rare cases, allergic reactions may occur in pigs after administration of the drug, manifesting as erythema, itching, respiratory symptoms, tissue edema, and partial rectal prolapse. In such cases, discontinue the drug, administer antihistamines, and apply symptomatic treatment.

3.4. Concurrent use with penicillins, cephalosporins, lincosamides, and macrolides is not recommended.

3.5. Slaughter of animals for meat is allowed no earlier than 8 days after the last administration of the drug.

Meat from animals slaughtered before this period may be used for feeding carnivorous animals.

Milk intended for human consumption must not be used during treatment and for 5 days after the last use of the drug.

4. Precautionary Measures

4.1. When handling the drug, standard personal hygiene and safety precautions should be observed.

5. Claims Procedure

5.1. In the event of complications following the use of the drug, its administration must be stopped, and the consumer should contact the State Veterinary Institution in their locality. Veterinary specialists will assess whether all instructions for use were followed. If negative effects of the drug on the animal are confirmed, the specialists will collect necessary samples, including at least three unopened vials from the same batch, draft a sampling report, and forward it to the State Institution "Belarusian State Veterinary Center" for compliance verification (220005, Republic of Belarus, Minsk, Krasnaya Street 19A, Tel.: 290-42-75).

6. Manufacturer Information

6.1. Production Cooperative "Biogel".

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

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

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

The instructions for use were developed by employees of PC "Biogel" (L.E. Yanshevskaya) and the Private Enterprise "Letyal" (A.N. Bezborodkin).