INSTRUCTIONS
for Use of the Veterinary Drug Letazitrovetum

1. General Information

1.1 The veterinary drug Letazitrovetum.

International non-proprietary name: azithromycin.

Dosage form: solution for intramuscular injection.

1.2 The veterinary medicinal product Letazitrovetum (hereinafter referred to as the product) is a clear liquid ranging in color from colorless to yellow.

1.3 Each 1.0 ml of the product contains 100 mg of azithromycin (as mono- or dihydrate) as the active ingredient, and excipients: propylene glycol, water for injection.

1.4 The product is packaged in 10, 50 or 100 ml vials made of colorless or dark glass, sealed with rubber stoppers and crimped with aluminum caps.

1.5 The product is stored and transported in the manufacturer's packaging in a place protected from direct sunlight at a temperature from 5 ºC to 25 ºC. Keep out of reach of children!

1.6 Shelf life of the product is 2 years from the date of manufacture if storage and transportation conditions are followed. After opening the vial, the product must be used within 24 hours, provided the remaining solution is stored at a temperature of 3 °C to 8 °C. Do not use after the expiration date. The product shall be disposed of in accordance with current legislation.

1.7 Dispensing conditions: without a prescription from a veterinary doctor.

2. Pharmacological Properties

2.1 Azithromycin, which is part of the product, is an antibiotic from the macrolide group, azalide subgroup, and has a broad spectrum of activity. In therapeutic doses, it has a bacteriostatic effect on gram-negative (*Mannheimia haemolytica*, *Pasteurella spp.*, *Bordetella spp.*, *Campylobacter spp.*, *Salmonella spp.*, *Escherichia coli*) and gram-positive bacteria (*Listeria monocytogenes*, *Staphylococcus spp.*, *Streptococcus spp.*, *Erysipelothrix rhusiopathiae*), some anaerobic bacteria (*Clostridium spp.*, *Fusobacterium necrophorum*), as well as mycoplasmas and chlamydia.

2.2 The mechanism of action of the product is associated with the inhibition of bacterial ribosomal protein biosynthesis (disruption of peptide bond formation between amino acids and the peptide chain). The product is well absorbed and quickly distributed in body tissues, reaching high concentrations that significantly exceed plasma levels.

2.3 High antimicrobial activity is ensured by the ability of azithromycin to penetrate and accumulate in leukocytes (granulocytes and monocytes/macrophages), with which it is transported to sites of inflammation, resulting in antibiotic concentration being six times higher at the inflammation site compared to intact tissues. After administration, the half-life ranges from 8 to 24 hours.

2.4 The product is mainly excreted unchanged in bile; a small portion is excreted in urine.

2.5 The product belongs to hazard class IV according to GOST 12.1.007-76 (low-hazard substances).

3. Directions for Use

3.1 The product is used for therapeutic purposes in pigs, young cattle and small ruminants for diseases of the respiratory, digestive, and genitourinary systems, skin and soft tissue pathologies, and other diseases caused by microorganisms sensitive to azithromycin.

3.2 The product is administered intramuscularly to cattle, small ruminants, and pigs at a dose of 1.0 ml per 20 kg of animal body weight (5 mg of azithromycin per 1 kg of body weight) once. If necessary, re-administration may be carried out after 3–5 days.

For animals weighing more than 300 kg, the dose should be divided so that the volume administered at one injection site does not exceed 7.5 ml.

3.3 The use of the product is prohibited in animals with renal and hepatic insufficiency, lactating animals, and in cases of individual sensitivity to azithromycin. It should be administered to pregnant animals with caution (under the supervision of a veterinary doctor).

3.4 When the product is used according to the instructions, no side effects or complications have been identified. A slight swelling may be observed at the injection site, which resolves quickly

and does not require treatment. If an allergic reaction occurs, the product is discontinued, and antihistamines and symptomatic therapy are prescribed.

3.5 In case of an overdose of the medicinal product, animals may exhibit anxiety, sleep disturbances, disorientation, and temporary hearing loss. In such cases, general measures to remove the product from the body and symptomatic treatment should be used.

3.6 When used with tetracyclines, the product's effect is enhanced, while it is reduced with lincosamides. The product is incompatible with heparin. The use of the product with cardiac glycosides is not recommended. The product should not be mixed in the same syringe with other drugs.

3.7 No specific effects were observed during initial administration or upon withdrawal of the product.

3.8 Dosage violations should be avoided.

3.9 Slaughter of pigs, young cattle and small ruminants for meat is allowed not earlier than 40 days after the last administration of the product. Meat from animals slaughtered before the specified period may be used for feeding fur-bearing animals.

4. Precautionary Measures

4.1 When working with the product, standard personal hygiene and safety precautions should be observed.

4.2 If the product or its components come into contact with skin or mucous membranes, rinse thoroughly with water.

5. Claims Procedure

5.1 In the event of complications following the use of the product, its application is discontinued, and the consumer contacts the state veterinary institution in their area. Veterinary specialists of this institution examine compliance with all rules for the use of the product according to the instruction. If the negative effect of the product on the animal's body is confirmed, samples in the required quantity are collected by veterinary specialists for laboratory testing and sent to the state institution "Belarusian State Veterinary Center" to confirm compliance with regulatory documents (Minsk, Krasnaya St. 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, Stolbtsovsky district, Nivnoye village.

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

The instruction for use was developed by employees of PC "Biogel" (L.E. Yanushevskaya) and the Private Enterprise "Letyal" (A.N. Bezborodkin).