

INSTRUCTIONS

for Use of the Veterinary Drug Product Letsulfatrim WP

1 General Information

1.1 The veterinary drug Letsulfatrim WP.

International Nonproprietary Name of the active pharmaceutical substance: sulfadiazine sodium (sulfadiazinum natriicum) and trimethoprim (trimethoprimum).

1.2 Dosage form: powder for oral administration and preparation of solution.

1.3 The veterinary medicinal product Letsulfatrim WP (hereinafter referred to as the product) is a powder ranging in color from white to light yellow.

Each 1 g of the product contains 200 mg sulfadiazine sodium, 40 mg trimethoprim, and excipient – dextrose.

1.4 The product is packed in metallized polyethylene bags with a net weight of 100, 500, or 1000 g.

1.5 The product is stored and transported in the manufacturer's packaging in a place protected from direct sunlight at a temperature from 2°C to 25°C. Keep out of reach of children.

1.6 Shelf life of the product is 3 (three) years from the date of manufacture, provided that storage and transportation conditions are met. Do not use after the expiration date. After expiration, the product must be disposed of in accordance with the law.

1.7 Dispensing conditions: without a veterinary prescription.

2 Pharmacological Properties

2.1 Sulfadiazine is a medium-duration sulfonamide. It disrupts the microorganisms' synthesis of essential growth factors – folic acid and other substances that include para-aminobenzoic acid. Sulfadiazine interferes with the microbial cell's formation of methionine, purine, and pyrimidine bases, which in turn disrupts the synthesis of nucleic acids and nucleoproteins. It can neutralize endotoxins in the body.

Sulfadiazine is absorbed slowly from the gastrointestinal tract, reaching its maximum concentration in the blood within 4–6 hours, binds weakly to plasma proteins, and is excreted slowly from the body. Due to its combination of anti-allergic, antipyretic, and bacteriostatic effects, sulfadiazine is used in various diseases accompanied by inflammation.

Trimethoprim is a synthetic derivative of diaminopyrimidine, active against gram-positive and gram-negative bacteria by blocking the reduction of dihydrofolic acid to tetrahydrofolic acid, which is essential for microbial growth. Its pharmacodynamics and pharmacokinetics are similar to those of long-acting sulfonamides.

2.2 The product is highly stable in acidic environments, is rapidly absorbed after oral administration, and penetrates all body tissues. Maximum blood concentration occurs within 1–3 hours and is maintained for 7 hours. High concentrations are achieved in the lungs and kidneys. It is excreted in large amounts in the urine.

2.3 The combination of sulfadiazine and trimethoprim has a stronger bacteriostatic and bactericidal effect on pathogenic microflora than either substance alone. The product is active against gram-positive and gram-negative bacteria, including *Escherichia coli*, *Clostridium spp.*, *Staphylococcus spp.*, *Streptococcus spp.*, *Salmonella spp.*, *Pasteurella spp.*, *Mannheimia haemolytica*, *Actinomyces spp.*, *Haemophilus spp.*, *Eimeria spp.*, and other pathogens sensitive to sulfadiazine sodium and trimethoprim.

2.4 The product belongs to low-hazard substances (Hazard Class IV according to GOST 12.1.007-76).

3 Directions for Use

3.1 The product is used for therapeutic purposes in young cattle, lambs, pigs, broiler chicks, and replacement layer pullets for the treatment of colibacillosis, pasteurellosis, salmonellosis, mycoplasmosis, staphylococcosis, coccidiosis, mixed bacterial infections, and other diseases caused by pathogens sensitive to the product's components.

3.2 The product is administered in the following doses:

- Young cattle under 6 months, lambs, and pigs: 1 g per 10 kg of body weight once daily with feed, milk, or drinking water for 3–7 days. At the start of treatment, a therapeutic dose is recommended twice at 12-hour intervals.
- Poultry: 400–1000 g per 1000 L of drinking water or 0.5 ml per 10 kg of body weight for 3–7 days. The solution is prepared based on the bird's daily water consumption. During the treatment period, birds should receive only water containing the product.

3.3 Side effects and complications are generally not observed when using the product. Rarely, allergic reactions (erythema, itching) may occur. If allergic reactions occur, discontinue use and administer antihistamines and calcium supplements.

3.4 The product is not recommended for animals with individual sensitivity to its components or when used in combination with sulfur-containing drugs or para-aminobenzoic acid derivatives.

3.5 The product is prohibited for use in poultry whose eggs are used for human consumption and in productive animals whose milk is used for human consumption.

3.6 Slaughter of animals and poultry for meat is allowed no earlier than 10 days after the last administration. Meat from animals and poultry slaughtered before the specified period may be used as feed for carnivorous animals.

4 Precautionary Measures

4.1 When working with the product, generally accepted personal hygiene practices and safety rules must be observed, as well as the use of personal protective equipment (respirator, gloves).

5 Claims Procedure

5.1 In case of complications after using the product, its use must be discontinued, and the consumer should contact the state veterinary institution in their area. Veterinary specialists will assess compliance with all rules of use according to the instructions. If adverse effects are confirmed, samples will be collected in the required quantity for laboratory testing, with at least three packaging units from the affected batch. A sample collection report is prepared and sent to the State Institution "Belarusian State Veterinary Center", 220005, Minsk, Krasnaya St., 19A, Tel.: 8-017-290-42-75, for conformity assessment against regulatory documents.

6 Manufacturer Information

6.1 Production Cooperative "Biogel".

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

Manufacturing site address: Republic of Belarus, Minsk Region, 222680, Stolbtsovsky District, Derevnoe village.

Manufactured by order of Private Enterprise "Letyal", 220075, Minsk, Inzhenernaya St., 1E.

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