APPROVED
Veterinary Medicines Council
Minutes No 118 of December 23, 2021

Instructions for Use
of the veterinary product Nosiheptide 1%-TRV

1. General Product Information

1.1 Nosiheptide 1%-TRV (Nosiheptidum 1%-TRV).

International nonproprietary name of the active pharmaceutical ingredient: Nosiheptide.

1.2 The product is a homogeneous grey to brown powder. Dosage form: oral powder.

1.3 Each g of the product contains 10 mg of nosiheptide, excipients (trilon B, silicon dioxide) and excipient (sucrose).

1.4 The preparation is packed in foil bags of 50, 100, 200, 250, 500, 1000 g and in multi-layer polyethylene bags of 5, 10, 20, 25, 30 kg with a package insert.

1.5 The veterinary product is stored in the manufacturer's package as per list B, in a dry, dark place at a temperature of 0 ° C to plus 25 ° C.

1.6 Shelf life is two years from the date of manufacture, subject to the conditions of storage and transportation. Once opened the package is stored no more than 10 days. Do not use the veterinary medicine after expiry date. Dispose of unused product in accordance with legal requirements.

2. Pharmacological Properties

2.1 The active ingredient of the veterinary product is nosiheptide, a bicyclic thiopeptide produced by the fungus *Streptomyces actuosus*. Nosiheptide has a marked antibacterial effect on Gram-positive bacteria and some Gram-negative bacteria, including all types of *Clostridium spp., Escherichia coli, Staphylococcus aureus, Streptococcus pyogenes haemolyticus, Streptococcus viridans, Streptococcus faecalis, Diplococcus pneumoniae, Salmonella spp*. and other. Does not have an adverse effect on obligate micro-organisms in the gastrointestinal tract.

2.2 The mechanism of antibacterial action of the veterinary product is to disrupt bacterial protein synthesis; it inhibits the function of elongation factors Tu and G and significantly reduces guanosine penta- and tetraphosphate synthesis in response to the stringent factor. This involves specific pentose methylation of the 23-s ribosome. Nosiheptide acts on the 50-s ribosomal subunits and binds the 23-s p-RNA complex to the L11 ribosomal protein.

2.3 When administered orally, nosiheptide is not absorbed from the gastrointestinal tract and forms a high concentration in the lumen. Nosiheptide does not accumulate in tissues and is excreted from the body unchanged.

2.4 The veterinary product is low-toxic, in the recommended doses has no mutagenic, sensitizing, embryotoxic and teratogenic effect, has no adverse effect on the quality of meat products.

3. Application Procedure

3.1 The veterinary product is used for treatment of young cattle, pigs, rabbits and poultry against clostridiosis, eschirichiosis, salmonellosis, staphylococcosis, streptococcosis and other infectious bacterial diseases caused by microorganisms sensitive to nosiheptide.

3.2 The preparation is administered as a group dose in mixture with feed for 14 days:

- young poultry - 250 g/1 t of feed;
- laying hens -200-250 g/1 t of feed;
- suckling piglets, growing pigs, fattening pigs, breeding sows and boars - 300-500 g/t feed
- gestating, lactating sows - 800-1000 g / 1 ton of feed;
- calves (up to 3 months of age) - 300-500 g/1 t feed;
- rabbits - 500-1000 g/1 t feed.

Depending on severity of pathological process the dose may be doubled and treatment course repeated.

3.3 In recommended doses the veterinary product does not cause adverse effects and is approved for use in pregnant and lactating animals.

Allergic reactions (dermatitis, itching, and swelling) are possible in animals with hypersensitivity. In case of allergic reaction the veterinary product shall be discontinued and antihistamines and calcium preparations (calcium chloride or calcium gluconate) shall be started.

3.4 The veterinary product is thermostable and does not lose its properties during granulation. It may be used concomitant with other preparations, coccidiostatics (eimeriostatics) and feed additives.

3.5 Livestock and poultry products (meat, eggs) after the last veterinary product administration may be used for food purposes without restrictions. The products obtained from sick animals and poultry as well as in case of forced slaughter shall be used as feed for carnivorous animals.

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4 Personal Precautions

4.1 Generally accepted personal hygiene and safety precautions should be observed when handling the product.

5 Claiming Procedure

5.1 In the event of complications following the use of the product, its use shall be discontinued and the user shall contact the State Veterinary Institution where the product is located. The veterinary staff of the institution shall investigate compliance with all rules for the use of the preparation in accordance with the instructions. In case of confirmation of the adverse effect on the animal's organism veterinary specialists take the samples in the required quantity for laboratory tests, draw up a sampling certificate and send it to the State Enterprise "Belarusian State Veterinary Centre" (220005, Minsk, Krasnaya Street 19A) for confirmation of compliance with the regulations.

6 Full name of the manufacturer

6.1 Stovek, Limited Liability Company, Republic of Belarus, 222660, Minsk Region, Stolbtsy, Zadvoryenskaya St., 2

Instructions for use are developed by employees of Stovek, LLC (Piotukh A.S., Plomodyalov D.A.).

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Department of Veterinary and Food
Control of the Ministry of Agriculture and
Food of the Republic of Belarus
Veterinary Medicinal Product Council
Approved

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