APPROVED
Veterinary Medicinal Product Council
Minutes No. 103 dated September 12, 2019

Summary of Veterinary Product Characteristics
TIAMULIN 80-TRV

1. GENERAL PRODUCT INFORMATION

1.1 Tiamulin 80-TRV.

1.2 Tiamulin 80-TRV is an antimicrobial veterinary product, oral powder, from white to white-yellow or light gray, without impurities, 1 g contains 800 mg of tiamulin hydrogen fumarate and excipients (dextrose, lactose).

1.3 The product is packed in the secondary packaging: foil bags of 100, 500, 1000, 5000 and 10000 g and in multilayer paper bags with a polyethylene insert of 10, 20, 25, 30 kg. Polyethylene bags liners must be packed hermetically.

1.4 Tiamulin 80-TRV is stored under the requirements of the list B, in a dry, dark place at a temperature from 0 ° C to plus 25 ° C. The shelf life in the manufacturer's packaging, subject to the shelf life of three years from the date of manufacture, the shelf life of once opened product is -35 days.

2. PHARMACOLOGICAL PROPERTIES

2.1 Tiamulin 80-TRV is an antibacterial veterinary product of the pleuromutilin group.

2.2 Tiamulin hydrogen fumarate, which is active substance of the veterinary product, has a broad spectrum of antibacterial action, suppressing protein synthesis of the microbial cell at the ribosomal level, and is highly active against:

- mycoplasmas, including - Mycoplasma hyopneumoniae, Mycoplasma hyosynoviae, Mycoplasma hyorhinis;
- brachispir - Brachyspira hyodysenteriae, Brachyspira pilosicoli;
- gram-positive aerobes, including aerobic cocci - Staphylococcus spp., Streptococcus spp. and anaerobes Clostridium perfringens;
- gram-negative anaerobes, including Lawsonia intracellularis, Bacteroides spp., Fusobacterium spp. and aerobes Actinobacillus pleuropneumoniae, Pasteurella multocida;

2.3 Tiamulin hydrogen fumarate has no effect on Enterobacteriaceae bacteria, including Salmonella spp. and Escherichia coli.

2.4 The mechanism of bacteriostatic action of tiamulin hydrogen fumarate is to suppress protein synthesis in a microbial cell at the ribosomal level.

2.5 Tiamulin hydrogen fumarate is rapidly absorbed in the gastrointestinal tract and rapidly metabolized in organs and tissues of the body. The maximum concentration is achieved in pigs' organisms - 2 hours after administration of the veterinary product and remains at a therapeutic level for 18-24 hours.

2.6 Tiamulin hydrogen fumarate is metabolized in the liver to inactive metabolites and is excreted from the body mainly in feces and, to a lesser extent, in urine.

2.7 Tiamulin 80-TRV, according to the degree of the exposure, belongs to low-hazard substances (hazard class 4 according to GOST 12.1.007-76).

3. DOSAGE AND INDICATION

3.1 Tiamulin 80-TRV is used as a therapeutic agent in pigs with dysentery, enzootic pneumonia, actinobacillus pleuropneumonia, proliferative enteropathy and intestinal spirochetosis.

3.2 The veterinary product is administered therapeutically orally individually or in groups in the following doses, in accordance with the table.

Table - Doses of the veterinary product

Disease	**Recommended dose**
dysentery	0.125-0.15 kg / ton of feed (5-6 mg of tiamulin per 1 kg of animal weight) for 3-5 days (if necessary, up to 10 days)

respiratory diseases (enzootic pneumonia, pleuropneumonia)	0.25 kg / ton of feed (10 mg of tiamulin per 1 kg of animal weight) for 10 days
ileitis	0.125-0.187 kg / ton of feed (5-7.5 mg of tiamulin per 1 kg of animal weight) within 14 days
spirochetosis	0.125 kg / ton of feed (5 mg of tiamulin per 1 kg of animal weight) for 7-10 days

3.3 To ensure uniform distribution of the veterinary product, the daily dose is mixed with a small amount of compound feed, and then, with thorough mixing, is added to the remaining feed, calculated for consumption during the day.

3.4 Missing the next dose of the veterinary product should be avoided, as this can lead to a decrease in therapeutic efficacy. In case of missing one dose, the administration of the veterinary product is resumed in the same dosage and according to the same regime.

3.5 Adverse effects, with the exception of cases of individual hypersensitivity to the components of the veterinary product, have not been identified. If symptoms of an allergic reaction appear in animals, the veterinary product is discontinued and, if necessary, symptomatic therapy, antihistamines and calcium preparations are prescribed.

3.6 In case of significant overdose, animals may experience diarrhea, anorexia, and nephrotoxic effects.

3.7 Contraindications. Do not use the veterinary product simultaneously with ionophore antibiotics, including monensin, narasin, salinomycin, maduramycin and veterinary products containing these compounds, as well as within 7 days before and after the treatment of pigs with these veterinary products.

3.8 Slaughter of pigs for meat is allowed no earlier than 10 days after the last administration of the veterinary product.

The meat of animals and poultry, forcedly killed before the expiration of the specified period, can be used to feed carnivores.

4 **PREVENTIVE MEASURES**

4.1 Generally accepted personal hygiene measures and safety rules should be observed when working with this veterinary product.

5 CLAIMING PROCEDURE

5.1 In case of complications after the use of the veterinary product, its use is discontinued and the consumer should apply to the State Veterinary Institution on the territory of its location. Veterinary specialists of this institution study compliance with all the rules for the use of the veterinary product in accordance with the instructions. After the confirmation of a veterinary product adverse effect to the animal, the veterinary specialists take samples in the required amount for laboratory tests, at least three unopened vials of the veterinary product from the batches that caused the complication, a sampling report is drawn up and sent to the State Institution "Belarusian State Veterinary Center" (220005, Minsk, Krasnaya Str. 19-a, tel. 290-42-75) for confirmation of compliance with regulatory documents.

6 FULL NAME OF MANUFACTURER

6.1 Stovek, LLC, Republic of Belarus, 222660, Minsk Region, Stolbtsy, Zadvoryenskaya St., 2

The Summary of Veterinary Product Characteristics was developed by the employees of Stovek, LLC: Ph.D. in veterinary science, associate professor A.Yu. Finogenov, T.A. Soboleva, Ph.D. in veterinary science E.G. Finogenova).

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12.09.2019 Minutes No. 103