

Summary of Veterinary Product Characteristics TETRAFID TRV

1. GENERAL PRODUCT INFORMATION

1.1 Tetrafid TRV.

1.2 TETRAFID TRV is an antimicrobial combined preparation for oral use, yellow powder without impurities, 1 g contains 200 mg of chlortetracycline hydrochloride and 50 mg of tiamulin hydrogen fumarate as active ingredients and excipients - starch, silicon dioxide, petrolatum oil, sucrose.

1.3 The product is packed in 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 TETRAFID 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. Shelf life - three years from the date of manufacture, subject to storage conditions.

After the expiration of the storage period, the unused veterinary product is disposed of in accordance with the requirements of the legislation.

2. PHARMACOLOGICAL PROPERTIES

2.1 TETRAFID TRV is a complex antibacterial veterinary product of a wide spectrum of action, containing active substances that exhibit synergistic joint action, providing a wide spectrum of antibacterial activity.

2.2 Chlortetracycline hydrochloride is a broad-spectrum antibiotic of the tetracycline group, active against most gram-positive and gram-negative microorganisms, including: *Staphylococcus spp.*, *Streptococcus spp.*, *Salmonella spp.*, as well as rickettsia and some types of mycoplasma. It does not affect *Pseudomonas aeruginosa*, *Proteus*, and most fungi.

2.3 Chlortetracycline is partially absorbed from the gastrointestinal tract, well distributed in all organs and tissues. The maximum concentration of the antibiotic in the body of pigs is detected 3 hours after administration the veterinary product.

2.4 Chlortetracycline is excreted in the urine and faeces.

2.5 Tiamulin hydrogen fumarate is a semi-synthetic antibiotic of the diterpene series. The mechanism of its antibacterial activity is to suppress the synthesis of bacterial protein at the level of the 50S ribosome subunit and is highly active against:

- mycoplasmas, including - *M. hyopneumoniae*, *M. hyosynoviae*, *M. hyorhinis*;
- brachispir - *B. hyodysenteriae*, *B. pilosicoli*;
- gram-positive aerobes, including aerobic cocci - *Staphylococcus spp.*, *Streptococcus spp.* and anaerobes (*Clostridium perfringens*).

2.6 Tiamulin does not act on bacteria of the Enterobacteriaceae family, including *Salmonella spp*

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

2.8 Tiamulin is eliminated mainly in feces..

2.9 TETRAFID TRV, according to the degree of exposure, is classified as a low-hazard substance (hazard class 4 according to GOST 12.01.007).

3. DOSAGE AND INDICATION

3.1 TETRAFID TRV is used as a therapeutic agent for pigs with respiratory and gastrointestinal diseases of bacterial and mycoplasma etiology, including dysentery, enterocolitis, enzootic pneumonia, actinobacillus pleuropneumonia, as well as other diseases caused by the association of microorganisms sensitive to the combination of active ingredients of the veterinary product.

3.2 The veterinary product is administered to pigs orally with feed in groups or individually during 5 days in the following doses, in accordance with the table.

Table – Dosage

| Method of administration | Recommended dose |
|---------------------------------|--|
| in groups | 200-400 g per 100 kg of feed (the dose of the veterinary product is 200 g / 100 kg of feed with a daily feed intake of 5% of the animal's body weight, the dose of the veterinary product is 400 g / 100 kg feed with a daily feed intake of 2.5% of the animal's body weight) |
| individually | 10 g per 100 kg of live weight (active substance- tiamulin hydrogen fumarate - 5 mg per 1 kg of body weight and active substance chlortetracycline hydrochloride - 20 mg per 1 kg of body weight) |

3.3 Adverse effects, with the exception of cases of individual hypersensitivity to the components of the product, have not been identified. In the event of symptoms of an allergic reaction in animals, the veterinary product is discontinued and, if necessary, symptomatic therapy, antihistamines and calcium preparations started.

3.4 Contraindications. The use of the veterinary product is contraindicated in animals with severe renal and hepatic insufficiency.

3.5 Do not use the veterinary product concomitantly with polyester ionophores (salinomycin, maduramycin, monensin, narasin, lazolacid and other coccidiostatics), aminoglycoside antibiotics, and also within 7 days before and 7 days after their administration, together with veterinary products containing calcium and magnesium, when interacting with which, the absorption of chlortetracycline decreases.

3.6 The administration of the veterinary product in pregnant sows and newborn animals is contraindicated.

3.7 Slaughter of pigs for meat is allowed no earlier than 20 days after the last administration of the veterinary product. The meat of animals, 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

6.2 The Summary of Veterinary Product Characteristics was developed by the employees of Stovek, LLC (T.A. Soboleva, V.V. Sobolev).

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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 | |
| Chairman | [Signature] |
| Secretary | [Signature] |
| Expert | [Signature] |
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