

Summary of Veterinary Product Characteristics

DOXYFID

1. GENERAL PRODUCT INFORMATION

1.1 Doxyfid

International non-proprietary name of active pharmaceutical ingredient: doxycycline.

Dosage form: oral powder for use in drinking water.

1.2 Appearance- yellowish to brown powder.

1.3 Each g contains doxycycline - 100 mg as active substance, excipients: starch, liquid paraffin, dextrose.

1.4 The veterinary product is packed in consumer packaging: foil bags of 100, 500, 1000, 5000 and 10000 g.

1.5 Doxyfid is stored according to list B in a dry, dark place at a temperature from 0 ° C to 25 ° C. Shelf life - three years from the date of manufacture, subject to storage conditions.

After the expiration of shelf life unused veterinary medicinal product should be disposed in accordance with local requirement

2. PHARMACOLOGICAL PROPERTIES

2.1 Doxycycline is a semisynthetic antibiotic of the tetracycline series with a bacteriostatic effect. It is active against gram-positive and gram-negative bacteria (Staphylococcus spp., Streptococcus spp., Listeria monocytogenes, Clostridium spp., Salmonella spp., Enterobacter spp., Moraxella spp., Klebsiella spp., Bordetella coli), as well as for Rickettsia spp., Treponema spp., Mycoplasma spp. and Chlamydia spp. Proteus, Pseudomonas aeruginosa, pathogenic fungi are not sensitive to the veterinary product.

2.2 The mechanism of action of the antibiotic -it exerts its action by inhibiting the protein synthesis of the microbial cell at the ribosome level.

2.3 Doxycycline is well absorbed from the gastrointestinal tract and is rapidly distributed in organs and tissues of the body. The maximum concentration in the blood serum is reached after 2-4 hours and is maintained at a therapeutic level for at least 18-24 hours after using the veterinary product.

2.4 Doxycycline is excreted from the body primarily in urine and faeces

3. INDICATIONS FOR USE

3.1 Doxyfid is used as a therapeutic agent in pigs with colibacillosis, salmonellosis, pasteurellosis, mycoplasmosis and other infectious diseases of the gastrointestinal tract, respiratory system and urinary tract caused by microorganisms sensitive to tetracycline veterinary products.

3.2 The veterinary product is used with feed, individually or in groups, for 5-7 days in doses according to the table:

Table - Veterinary product dosage

| Class of Stock | Recommended dose | |
|----------------|--|--|
| | Individually | In groups |
| Pigs | 0.1 g of the veterinary product (10 mg by API) per 1 kg of animal weight | 2.5 kg of the veterinary product per 1 TNE of feed (250 mg per 1 kg of feed) |

3.3 Adverse reactions, except of cases of individual hypersensitivity to the components of the veterinary product, have not been identified. If symptoms of an allergic reaction appear, the veterinary product is discontinued and, if necessary, symptomatic therapy is prescribed.

3.5 Contraindications. Increased individual sensitivity of animals to the components of the veterinary product. It is forbidden to use animals with severe impaired renal and hepatic function, farrowing sows.

3.5 The effectiveness of the veterinary product decreases with concomitant use with antibiotics that disrupt the synthesis of the cell wall (penicillins, cephalosporins), quinolones, as well as with veterinary products and feed additives containing calcium, magnesium, iron and aluminum compounds (due to a possible impairment of absorption).

3.6 Slaughtering of pigs for human consumption is allowed no earlier than 20 days after the last use of the veterinary product.

The meat of animals that were forcedly killed before the expiration of the specified period can be used as feed for 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 for TrionisVet, LLC, 141092, Russia, Moscow region, Korolev, md. Yubileynyj, st. Lesnaya, 14, office 5. The Summary of Veterinary Product Characteristics was developed by the employees of TrionisVet, LLC (A.Yu. Finogenov, T.A. Soboleva, E.G. Finogenova).

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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] |
| 14/03/2019. Minutes No. 100 | |