APPROVED
Veterinary Medicinal Product Council
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Summary of Veterinary Product Characteristics

DOXYGIL 50

1. GENERAL PRODUCT INFORMATION

1.1 Doxygil 50.
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 hyclate - 500 mg as active substance, excipients: sodium citrate, citric acid, dextrose.
1.4 The veterinary medicinal product is packed in consumer packaging: foil bags of 100, 500, 1000, 5000 and 10000 g.
1.5 Doxygil 50 is stored according to list B in a dry, dark place at a temperature from 0 ° C to 25 ° C. Shelf life - 3 (three) years from the date of manufacture, subject to storage and transportation conditions.
After the expiration of shelf life unused veterinary medicinal product should be disposed in accordance with local requirement.

2. PHARMACOLOGICAL PROPERTIES

1.1 Doxycycline is a semisynthetic tetracycline derivative (oxytetracycline derivative). Active against gram-positive and gram-negative microorganisms, incl. *Actinobacillus pleuropneumoniae, Clostridium spp., Escherichia coli, Staphylococcus spp., Streptococcus spp., Haemophilus spp., Pasteurella spp., As well as Mycoplasma spp., Rickettsia spp., Chlamydia spp*. Proteus, Pseudomonas aeruginosa, pathogenic fungi are not sensitive to the veterinary medicinal product.
2.2 The mechanism of the bacteriostatic action of the antibiotic -it exerts its action by inhibiting the protein synthesis by reversible binding to the 30S ribosomal subunit of microorganisms sensitive to the veterinary medicinal product.
2.3 Doxycycline is well absorbed into the bloodstream from the gastrointestinal tract and widely distributed in the organisms. The maximum concentration of the antibiotic 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 medicinal product.
2.4 Doxycycline is excreted primarily in faeces and in urine, in poultry – in eggs.

3. INDICATIONS FOR USE

3.1 Doxygil 50 is used as a therapeutic agent in calves, pigs and poultry for colibacillosis, salmonellosis, pasteurellosis, mycoplasmosis and other infectious diseases of the gastrointestinal tract, respiratory system, genitourinary system caused by microorganisms sensitive to doxycycline.
3.2 The veterinary medicinal product is administered to animals and poultry individually or in groups in drinking water, in the following doses:
- calves up to 3 months - a single dose - 0.10 g per 10 kg of animal body weight, twice a day in drinking water for 3-5 days;
- pigs - 0.2 g of the veterinary medicinal product per 10 kg of animal body weight, twice a day in drinking water for 4-6 days;
- poultry - 20-40 mg per 1 kg of body weight in drinking water for 3-5 days.
The following formula can be used to calculate the concentration of the product in drinking water:

$$\frac{ml\ product/\ kg\ body \times \text{mean body weight (kg) of animals to be treated}}{\text{mean daily water consumption (l) per animal}} = \text{ml product per l}$$

3.3 During the period of treatment, pigs and poultry (group use to be treated) should not have access to other water sources than the medicated water. Medicated drinking water should be refreshed or replaced every 24 hours

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

3.5 Contraindications. Increased individual sensitivity of animals to the components of the veterinary medicinal product. It is forbidden to use animals with severe impaired renal and hepatic function, as well as poultry, the egg of which is used for human consumption.

The veterinary medicinal product is not recommended for use in animals in the second trimester of gestation.

3.6 The veterinary medicinal product should not be used simultaneously with antibiotics of the penicillin and cephalosporin groups, as well as with veterinary medicinal products containing calcium, magnesium and bismuth.

3.7 Slaughtering of poultry for human consumption is allowed no earlier than 7 days, and pigs and calves - no earlier than 20 days after the last use of the veterinary medicinal product.

Meat of animals and poultry, forced to be 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 medicinal product.

5 CLAIMING PROCEDURE

5.1 In case of complications after the use of the veterinary medicinal 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 medicinal product in accordance with the instructions. After the confirmation of a veterinary medicinal 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 medicinal 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, Limited Liability Company, Republic of Belarus, 222660, Minsk Region, Stolbtsy, Zadvoryenskaya St., 2 for TrionisVet, 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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