APPROVED
Veterinary Medicinal Product Council
dated March 14, 2019 Minutes No. 100

Summary of Veterinary Product Characteristics

DOXICOLIN AQUA

1. GENERAL PRODUCT INFORMATION

1.1 Doxicolin aqua.

1.2 Doxicolin aqua is an antibacterial veterinary product, solution from brown to dark brown, each ml contains 200 mg of doxycycline hyclate and 1 000 000 IU of colistin sulphate as active ingredients, and excipients - citric acid, lactic acid, highly purified water.

1.3 The veterinary product is packed in polymer containers (polyethylene, polymer bottles or polyethylene canisters) of appropriate capacity with screw tamper proof caps, 100, 500, 1000, 2000, 3000, 5000 and 10000 ml each.

1.4 Doxicolin aqua is stored according to list B in a dry, dark place at a temperature from + 5 ° C to + 25 ° C. Shelf life is two years from the date of manufacture, subject to storage conditions.

2. PHARMACOLOGICAL PROPERTIES

2.1 Doxicolin aqua is a combined broad-spectrum antimicrobial veterinary product active against Streptococcus spp., Haemophilus spp., Escherichia coli, Clostridium spp., Listeria monocytogenes, Actinomyces spp., Enterobacter spp., Staphylococcus spp., Yersinia spp., Rickettsia spp., Mycoplasma spp., Bordetella spp., Pasteurella spp., Salmonella spp., Klebsiella spp. and others. Pseudomonas aeruginosa, Proteus spp., Serratia spp., most strains of Bacteroides fragilis are hyposensitive to the veterinary product action.

2.2 Doxycycline hyclate is an antibiotic from the group of semi-synthetic tetracyclines. Acts on gram-positive and gram-negative microorganisms. The mechanism of action is based on inhibition of the synthesis of nucleic acids and proteins of a bacterial cell.

2.3 Colistin sulphate is a cyclic polypeptide antibiotic synthesized by the aerobic spore-forming bacillus Bacillus polymyxa and acting on gram-negative microorganisms. The mechanism of action of colistin sulphate is to disrupt the permeability of the bacterial cell wall by combining with lipoproteins, which leads to the loss of amino acids, inorganic ions, purines and pyrimidines, leading to the death of the bacterial cell. Colistin sulphate reduces the effect of bacterial endotoxins in tissue fluids.

2.4 After oral administration, doxycycline is well absorbed in the gastrointestinal tract, reaching therapeutic plasma concentrations after 2 hours and remaining at a therapeutic level for 18-20 hours, easily penetrates into most organs and tissues, splitting in the liver with the formation of inactive metabolites, excreted from the body mainly in urine. By binding to blood proteins, it easily penetrates into most tissues. Colistin sulphate is practically not absorbed in the gastrointestinal tract and does not accumulate in muscle tissue and eggs; it is excreted from the body in faeces.

2.5 The veterinary product is characterized by high bioavailability and low toxicity. It is excreted from the body mainly in faeces and urine.

3. INDICATIONS FOR USE

3.1 Doxicolin aqua is used as a therapeutic agent in pigs and poultry (broiler chickens, replacement chickens and laying hens, goslings, turkey poultry and ducklings) for pneumonia of bacterial ethology, hemophilosis, colibacillosis (colibacillosis), and other diseases of salmonellosis caused by microorganisms sensitive to colistin and doxycycline.

3.2 The veterinary product is administered orally with drinking water individually or in a group way for 5 days in the following doses, in accordance with the table

Table - Doses of the veterinary product

Class of Stock	Recommended dose

	Individually	Group method
Poultry	0.1-0.2 ml of the veterinary product per 1 kg of body weight	500 ml of the veterinary product per 1000 l of water
Pigs	0.5-1 ml of the veterinary product per 10 kg of body weight BID	1-1.5 l of the veterinary product per 1000 l of water

For poultry, if necessary, the treatment course is repeated after 5 days.

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.

3.5 Adverse reactions, with the exception of cases of individual hypersensitivity to the components of the veterinary product, have not been identified. In case of symptoms of an allergic reaction in animals, the veterinary product is discontinued and, if necessary, symptomatic therapy is prescribed. Long-term treatment may result in dysbiosis onset.

3.5 Contraindications. The use of the veterinary product is contraindicated in case of hypersensitivity to substances, with severe renal and hepatic insufficiency. Is forbidden to use the veterinary product in poultry, whose eggs are used for human consumption.

3.6 The veterinary product should not be used simultaneously with penicillins, cephalosporins, macrolides, tetracyclines, non-steroidal anti-inflammatory veterinary products.

3.7 Slaughtering of animals and poultry for human consumption is allowed no earlier than 14 days after the last use of the veterinary product.

Meat of animals and poultry, 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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