

Summary of Veterinary Product Characteristics
CIPROFLOXACIN AQUA

1. GENERAL PRODUCT INFORMATION

1.1 Trade name: Ciprofloxacin Aqua.

International non-proprietary name: ciprofloxacin.

1.2 Dosage form: oral solution

1.3 Ciprofloxacin Aqua is an antibacterial veterinary product, clear from light yellow to light brown solution with a precipitate, dissolving after shaken, each ml contains 200 mg of ciprofloxacin as an active substance and excipients - formic acid, highly purified water.

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

1.5 Ciprofloxacin Aqua is stored with precautions according to list B in a dry, dark place at a temperature from + 5 ° C to + 25 ° C. The shelf life, if the storage conditions are observed in the sealed manufacturer's packaging, is two years from the date of manufacture, after opening the packaging - 28 days.

2. PHARMACOLOGICAL PROPERTIES

2.1 Ciprofloxacin Aqua belongs to the antibacterial veterinary products of the fluoroquinolone group and has a wide spectrum of antimicrobial and anti-mycoplasma action and acts both on proliferating microorganisms and vegetative bacteria. Active against gram-positive and gram-negative bacteria, including:

Staphylococcus spp., Streptococcus spp., Clostridium spp., Actinobacillus spp., Escherichia coli, Salmonella spp., Enterobacter spp., Haemophilus spp., Klebsiella spp., Pasteurella spp., Bordetella spp., Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, Campylobacter spp., Erysipelothrix rhusiopathiae, Bacteroides, Fusobacterium necrophorum, Mycoplasma spp. and other.

2.2 The mechanism of the bactericidal action of ciprofloxacin is in blocking bacterial DNA gyrase, which leads to disruption of bacterial division due to inhibition of DNA synthesis, as well as in the development of morphological changes in the cell wall and membranes of the microbial cell.

2.3 Acts on gram-negative microorganisms in rest and division phases, has an effect on gram-positive microorganisms only in division phase.

2.4 Does not have embryotoxic, teratogenic and hepatotoxic effects.

2.5 When the veterinary product is administered orally, ciprofloxacin is well and rapidly absorbed in the gastrointestinal tract and penetrates into all organs and tissues, reaching the maximum concentration in the blood, depending on the type of animal, after 0.5- 2.5 hours (bioavailability over 70%). The therapeutic concentration of ciprofloxacin in the blood of animals is maintained for 7-10 hours. It is excreted from the body of animals mainly in urine unchanged, as well as in the form of metabolites, the rest is excreted by the gastrointestinal tract (with faeces and bile).

2.6 Ciprofloxacinum Aqua, according to the degree of exposure to the body, refers to low-hazard substances (hazard class 4 according to GOST 12.1.007-76).

3. INDICATIONS FOR USE

3.1 Ciprofloxacin Aqua is used as a therapeutic agent in poultry and pigs for treatment of the gastrointestinal and respiratory tract (colibacillosis, pasteurellosis, mycoplasmosis etc.), the genitourinary system, pig erysipelas, necrobacteriosis and other diseases caused by microorganisms, sensitive to ciprofloxacin.

3.2 The veterinary product is administered orally BID for 3-5 days in the following doses, in accordance with the table:

| Class of Stock | Recommended dose | |
|----------------|------------------|-------------------------|
| | Individually | Group use to be treated |

| | | |
|---------|------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------|
| Pigs | 0.5 ml of the veterinary product per 10 kg of body weight or 0.05 ml of the veterinary product per 1 kg of body weight | 100 ml of the veterinary product per 300-400 l of drinking water or 250-330 ml of the veterinary product per 1000 l of drinking water |
| Poultry | ----- | 100 ml of the veterinary product for 300-400 l of drinking water or 250-330 ml of the veterinary product per 1000 l of drinking water |

3.3 The duration of treatment and the dose depends on the severity of the disease. In cases of salmonellosis, concurrent infections and chronic forms of diseases - at least 5 days.

3.4 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.

3.6 The use of the veterinary product is contraindicated in case of hypersensitivity to fluoroquinolones, with severe renal and hepatic insufficiency. It is prohibited to use the veterinary product in laying hens during the period of oviposition and replacement chickens at least 2 weeks before the start of oviposition due to the accumulation of ciprofloxacin in eggs and animals during gestation.

3.7 The veterinary product should not be used simultaneously with bacteriostatic antibiotics (macrolides, tetracyclines, etc.), as well as with theophylline, non-steroidal anti-inflammatory veterinary products, magnesium and calcium preparations.

3.8 Slaughtering of pigs for human consumption is allowed no earlier than 14 days; poultry - not earlier than 12 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, 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).

[Stamp]:

| | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| 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] |
| 30/10/ 2020. Minutes No. 111 | |