

**Summary of Veterinary Product Characteristics  
FLOROL 10% AQUA-TRV**

**1. GENERAL PRODUCT INFORMATION**

1.1 Florol 10% aqua-TRV.

1.2 Florol 10% aqua-TRV is an antibacterial veterinary product in the form of oral solution, clear viscous from light yellow to brownish yellow solution, each ml contains 100 mg of florfenicol as an active substance and excipients - polyethylene glycol, propylene glycol, 1-methyl 2-pyrrolidone.

1.3 The veterinary product is packed in polymer containers of 100, 500; 1000, 2000, 3000, 5000 and 10000 ml.

1.4 The veterinary product is stored according to list B in a dry, dark place at a temperature from + 5 ° C to + 25 ° C. Shelf life, subject to storage conditions in a closed manufacturer's packaging - two years from the date of manufacture, after opening the package - 28 days

**2. PHARMACOLOGICAL PROPERTIES**

2.1 Florol 10% aqua-TRV belongs to the broad-spectrum antibacterial veterinary products of the fenicol group. Florfenicol is an antibiotic derived from thiamphenicol that has a bacteriostatic effect against gram-positive and gram-negative bacteria, including: gram-negative aerobic bacteria - Pasteurella spp., Bordetella bronchiseptica, Escherichia coli, Salmonella spp., Klebsiella spp., Haemophilus spp.; gram-positive aerobic cocci - Streptococcus spp., Staphylococcus spp., as well as Fusobacterium necrophorum, and Mycoplasma spp.

2.2 The mechanism of action of florfenicol is based on the suppression of bacterial protein synthesis by binding to the 70S ribosome subunit. Veterinary product resistance develops relatively slowly, and cross-resistance to other chemotherapeutic agents does not occur.

2.3 When administered orally, florfenicol is well absorbed from the gastrointestinal tract and penetrates into most organs and tissues, but does not cross the blood-tissue barriers. The bioavailability of florfenicol is 88% in pigs, 55% in poultry, the maximum concentration in blood serum is reached 1-1.5 hours after the veterinary product is applied and lasts for 24 hours. It is excreted from the body mainly in urine, and less in faeces.

2.4 Florol 10% aqua-TRV, according to the degree of exposure to the body, is classified as a low-hazard substance (hazard class 4 according to GOST 12.1.007-76).

**3. INDICATIONS FOR USE**

3.1 Florol 10% aqua-TRV is used as a therapeutic agent in pigs and poultry for treatment colibacillosis, salmonellosis, pasteurellosis, staphylococcosis and other infectious diseases of poultry caused by microorganisms susceptible to florfenicol, as well as for pleuropneumonia, atrophic rhinitis and porcine infections.

3.2 The veterinary product is administered orally in drinking water in the following doses, in accordance with the table.

Table - Doses of the veterinary product

<b>Class of Stock</b>	<b>Recommended dose</b>
Pigs	5 ml of the veterinary product per 100 kg or 0.05 ml per 1 kg of animal weight (according to API - 5 mg per 1 kg of animal weight) for 7 days
Chickens up to 4 weeks	1 l of the veterinary product per 1000 l of water (according to API - 20 mg per 1 kg of animal weight) for 3 days

Poultry - other age categories	2 l of the veterinary product per 1000 l of water (according to API - 20 mg per 1 kg of animal weight) within 3 days, in case of salmonellosis treatment is performed for 5 days
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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. The daily dose can be divided into two equal parts and set at intervals of 12 hours. If a precipitate appears, the solution should be thoroughly mixed before use.

The active substance of the veterinary product can precipitate if the concentration of florfenicol in water exceeds 1 g per 1 l, which corresponds to 10 ml of the veterinary product per 1 l of water.

3.4 Florol 10% aqua-TRV does not cause side effects in recommended doses. With frequent use or overdose, diarrhoea, anorexia and allergic reactions can occur. If allergic reactions develop, the veterinary product is cancelled and antihistamines (diphenhydramine, allergic) and calcium preparations (calcium chloride, calcium gluconate, calcium borogluconate) are prescribed.

3.5 It is forbidden to use the veterinary product in sows during pregnancy and lactation, boars-producers, laying hens, whose eggs are used for human consumption, animals with renal and hepatic insufficiency, as well as with hypersensitivity to florfenicol

3.6 The veterinary product should not be used simultaneously with thiamphenicol, chloramphenicol, fluoroquinolones, cephalosporins and antibiotics of the penicillin group. It is not recommended to mix the solution with other medicinal products.

3.7 Slaughtering of pigs for meat is allowed no earlier than after 14 days; poultry - not earlier than 6 days after the last use of the veterinary product.

Meat of animals and poultry, forcibly 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.

The Summary of Veterinary Product Characteristics was developed by the employees of Stovek, LLC (A.Yu. Finogenov, T.A. Soboleva, E.G. Finogenova).

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