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

Summary of Veterinary Product Characteristics
FLOREZOL

1. GENERAL PRODUCT INFORMATION

1.1 Florezol

1.2 Florezol is an antibacterial veterinary medicinal product in the form of a solution for injection, clear to light yellow solution, each ml contains 400 mg of florfenicol as an active substance and excipients - propylene glycol, polyethylene glycol, polyvinylpyrrolidone.

1.3 The veterinary medicinal product is packed in glass vials of appropriate capacity of 10, 20, 30, 50, 100, 200, 400 ml, hermetically sealed with rubber stoppers and reinforced with flip-off screw tamper proof caps.

1.4 Florezol is stored in a dry, dark place at temperatures from + 5 ° C to + 25 ° C. Shelf life is two years from the date of manufacture, subject to storage conditions. After opening the bottle, the veterinary medicinal product is stored for 3 days.

2. PHARMACOLOGICAL PROPERTIES

2.1 Florfenicol is a synthetic broad-spectrum antibiotic that has a bacteriostatic effect against Gram-positive and Gram-negative bacteria, including *Pasteurellci spp., Haemophilus spp., Escherichia coli, Salmonella spp., Klebsiella spp., Staphylococcus spp., Streptococcus spp., Fusobacterum necrophorum,* as well as *Moraxella bovis* и *Mycoplasma spp.*

2.2 The mechanism of action of florfenicol is based on the suppression of bacterial protein synthesis by binding to the 50S subunit of ribosomes.

2.3 The veterinary medicinal product is well absorbed from the injection site and penetrates into the organs and tissues of the body, is metabolized in the liver.

2.4 Florfenicol is excreted mainly in urine.

3. INDICATIONS FOR USE

3.1 Florezol is used as a therapeutic agent in pigs, cattle and small stock for infectious diseases caused by pathogens sensitive to the action of the veterinary product.

3.2 The veterinary medicinal product is administered intramuscularly or subcutaneously, in the following doses, in accordance with the table.

Class of Stock	**Recommended dose**
Pigs	0.75 ml of the veterinary medicinal product per 20 kg of body weight, intramuscularly, 48 hours apart
Cattle and small stock	0.75 ml of the veterinary medicinal product per 15 kg of body weight, intramuscularly, 48 hours apart
	1.5 ml of the veterinary medicinal product per 15 kg of body weight, subcutaneously, once a day

3.3Due to the possible pain reaction, the maximum volume of the veterinary medicinal product at injection site should not exceed 10 ml

3.4 Adverse reactions, with the exception of cases of individual hypersensitivity to the components of the veterinary medicinal product, have not been identified. In case of symptoms of an allergic reaction in animals, the veterinary medicinal product is discontinued and, if necessary, symptomatic therapy is prescribed.

3.5 Contraindications. The use of the veterinary medicinal product is contraindicated in case of hypersensitivity to florfenicol. It is forbidden to use the veterinary medicinal product for productive

animals, whose milk is used for human consumption, animals during pregnancy, adult boars and bulls-producers during the mating period.

3.6 The veterinary medicinal product should not be used simultaneously with thiamphenicol, fluoroquinolones, cephalosporins and antibiotics of the penicillin group.
3.7 Slaughtering of pigs for human consumption is allowed no earlier than 14 days, cattle and small stock no earlier than 34 days after the last intramuscular injection and 42 days after the last subcutaneous injection of the veterinary medicinal 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 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

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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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