APPROVED
Veterinary Medicinal Product Council
Minutes No. 105 dated January 09, 2020

Summary of Veterinary Product Characteristics
AMOCOL 50

1. GENERAL PRODUCT INFORMATION

1.1 AMOCOL 50.

1.2 AMOCOL 50 is a combined antimicrobial veterinary product, from white to yellow oral powder, 1 g contains 500 mg of amoxicillin trihydrate and 4 million IU of colistin sulfate as active ingredients and excipients - sodium citrate, citric acid, sodium carbonate anhydrous, dextrose.

1.3 The product is packed in foil bags of 100, 500, 1000, 5000 and 10000 g and in multilayer paper bags with a polyethylene insert of 10, 20, 25, 30 kg. Polyethylene bags liners must be packed hermetically.

1.4 AMOCOL 50 is stored according to the requirements of the list B in a dry, dark place at a temperature from 0 ° C to plus 25 ° C. The shelf life in the manufacturer's packaging, subject to the shelf life of three years from the date of manufacture, the shelf life of once opened product is 35 days

2. PHARMACOLOGICAL PROPERTIES

2.1 Amoxicillin is a penicillin group semi-synthetic antibiotic. It has a wide spectrum of antimicrobial action. *Erysipelothrix rhusiopathiae, Staphylococcus spp., Corynebacterium spp., Clostridium spp., Salmonella spp., Fusobacterium necrophorum, Haemophilus spp., Pasteurella spp., Proteus spp., Escherichia coli* and other microorganisms are sensitive to Amoxicillin.

2.2 Amoxicillin inhibits the synthesis of the bacterial cell wall by inhibiting the enzymes transpeptidase and carboxypeptidase, which leads to disruption of the osmotic balance and death of bacteria.

2.3 Amoxicillin is well absorbed into the bloodstream from the gastrointestinal tract and is rapidly distributed in the organs and tissues. The maximum concentration in blood plasma is reached within 1-2 hours after administration. It is excreted with urine and bile.

2.4 Colistin sulfate is a mixture of polypeptides produced by several strains of Bacillus polymyxia. It has a bactericidal effect against some aerobic gram-negative microorganisms.

2.5 The mechanism of action of colistin sulfate is associated with a damage of the permeability of the cytoplasmic membrane of bacteria sensitive to it.

2.6 The colistin sulfate is not destroyed and is practically not absorbed into the blood in the gastrointestinal tract of animals. It does not accumulate in organs and tissues; it is excreted with feces.

2.7 The product belongs to low-hazard substances (hazard class 4 according to GOST 12.1.007-76) according to its exposure.

3. DOSAGE AND INDICATION

3.1 AMOCOL 50 is used as a therapeutic agent for piglets, calves and poultry with colibacillosis, salmonellosis, pasteurellosis, hemophilia, necrobacteriosis, swine erysipelas and other diseases, the causative agents of which are sensitive to the components of the veterinary product .

3.2 The veterinary product is used for piglets, calves and poultry in group or individual ways with water or milk for drinking for 3-5 days in the following doses:

- calves, piglets 3.0 g of the veterinary product per 100 kg of body weight, bid;
- poultry 300 g of the veterinary product per 1000 liters of drinking water. For a poultry, a solution of the veterinary product is prepared based on the need for water for one day.

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 effects, with the exception of cases of individual hypersensitivity to the components of the veterinary product, have not been identified. If symptoms of an allergic reaction appear, the veterinary product is discontinued and, if necessary, symptomatic therapy is started.

3.5 Contraindications. Increased individual hypersensitivity to penicillins. It is contraindicated to use the veterinary product in poultry, whose egg is used as food for humans. Not recommended for adult animals with developed cicatricial digestion.

3.6 Must not be used simultaneously with tetracyclines, macrolides and ulfonamides.

3.7 Slaughter of animals and poultry for meat is allowed no earlier than 4 days after the last administration of the veterinary product.

The meat of animals and poultry, forcedly killed before the expiration of the specified period, can be used to feed 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, Limited Liability Company, 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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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*]
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Expert [*Signature*]
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