APPROVED
Veterinary Medicinal Product Council
Minutes No. 114 dated April 21, 2021

Summary of Veterinary Product Characteristics
AMOCLAV

1. GENERAL PRODUCT INFORMATION

1.1 Amoclav.

International non-proprietary names of active pharmaceutical ingredients: amoxicillin, clavulanic acid.

Dosage form: oral powder

1.2 Amoclav is a combined antimicrobial veterinary product, from white to yellow oral powder, 1 g contains 500 mg of amoxicillin trihydrate and 125 mg of clavulanic acid (in the form of potassium clavulanate) as active ingredients and excipients - sodium citrate, citric acid, dextrose.

1.3 The veterinary product is packed in consumer packaging: foil bags of 100, 500, 1000, 5000 and 10000 g.

1.4 Amoclav is stored according to the requirement of the list B in a dry, dark place at a temperature from 0 ° C to plus 25 ° C. The shelf life is three years from the date of manufacture, subject to the storage terms.

2. PHARMACOLOGICAL PROPERTIES

2.1 Amoxicillin is a penicillin group semi-synthetic antibiotic. It has a wide spectrum of bactericidal action against gram-positive bacteria (Actinomyces spp., Bacillus anthracis, Clostridium spp., Corynebacterium spp., Erysipelothrix rhusiopathiae, Listeria monocytogenes, Staphylococcus spp., Streptococcus spp., Streptococcus spp. coli, Salmonella spp., Fusobacterium necrophorum, Haemophilus spp., Moraxella spp., Pasteurella spp., Proteus mirabilis). The veterinary product has no effect on penicillinase-forming strains of microorganisms from the genera Klebsiella and Enterobacter, as well as Pseudomonas.

2.2 Amoxicillin inhibits the synthesis of the bacterial cell wall, inhibiting the enzymes transpeptidase and carboxypeptidase and causes an imbalance in the osmotic balance, which leads to the death of bacteria during the growth stage.

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.

2.4 Clavulanic acid (potassium clavulanate) is a beta-lactamase inhibitor. It contains a beta-lactam structure similar to that of beta-lactam antibiotics. It has its own antibacterial activity. Like other beta-lactams, clavulanic acid is able to bind to penicillin-binding proteins (PBPs) of gram-positive and gram-negative bacteria and promote lysis of a bacterial wall.

3. DOSAGE AND INDICATION

3.1 Amoklav is used as a therapeutic agent for pigs and poultry with escherichiosis, salmonellosis, pasteurellosis and other infections of the gastrointestinal, respiratory tract and urinary tract caused by microorganisms sensitive to amoxicillin.

3.2 The veterinary product is used in pigs and poultry (broiler, replacement laying hens, goslings, turkey poults and ducklings) in a group or individual way mixed with feed, water or milk for 3-5 days in the following doses:

- a poultry under the age of 10 days - 5 g/100 L of water (at the rate of 0.04 g/kg of body weight);
- a poultry older than 10 days of age - 10 g/100 l of water (at the rate of 0.04 g/kg of body weight);

- pigs - 0.4-1 g of the veterinary product per 50 kg of body weight, bid.

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 forbidden to use the veterinary product in poultry, whose egg is used as food for humans.

3.6 Must not be used simultaneously with sulfonamides, antibiotics of the tetracycline group, amphenicols, macrolides and lincosamides.

3.7 Slaughter of poultry for meat is allowed no earlier than 8 days, and pigs - no earlier than 21 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 for Trionis Vet, 141092, Russia, Moscow Region, Korolev, md. Yubileiny, Lesnaya St., 14, office 5

The Summary of Veterinary Product Characteristics was developed by the employees of Trionis Vet, (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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