

**Summary of Veterinary Product Characteristics  
AMOXICILLIN 80-TRV**

**1. GENERAL PRODUCT INFORMATION**

1.1 Amoxicillin 80-TRV.

1.2 Amoxicillin 80-TRV is an antimicrobial veterinary product, from white to yellow- or gray-white oral powder, without impurities, 1 g contains 800 mg of amoxicillin trihydrate as an active ingredient and excipients: sodium anhydrous carbonate, sodium hydroxide, 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 Amoxicillin 80-TRV is stored according to 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 ansemisynthetic penicillin group antibiotic, which has a wide spectrum of antibacterial action. It is active against many microorganisms, including:

- gram-positive: aerobic cocci - *Staphylococcus spp.*, *Streptococcus spp.*, aerobic non-spore-forming bacteria - *Listeria monocytogenes*, anaerobic spore-forming bacteria - *Clostridium spp*, *Actinomyces spp.*, anaerobic non-spore-forming - *Erysipelothrix rhusiopathiae*, *Corynebacterium spp.*

- gram-negative: aerobic cocci - *Actinobacillus spp.*, aerobic spirochetes - *Leptospira spp .;* aerobic bacteria - *Escherichia coli*, *Salmonella spp.*, *Klebsiella spp.*, *Haemophilus spp.*, *Pasteurella spp.*, *Bordetella bronchiseptica*, *Moraxella spp.*, *Proteus mirabilis*, anaerobic non-spore-forming - *Fusobacterium necrophorum*

2.2 Amoxicillin is not active against microorganisms that produce  $\beta$ -lactamase and does not act on penicillin-resistant strains of microorganisms.

2.3 The mechanism of the bactericidal action of the antibiotic is to interfere with the synthesis of the cell wall by inhibiting the enzymes transpeptidase and carboxypeptidase, causing a damage of the osmotic pressure in the bacterial cell, which leads to the death of bacteria at the stage of their growth.

2.4 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 of the veterinary product.

2.5 With a constant intake of an antibiotic with water or food, therapeutic concentrations are maintained in the body throughout the entire course of treatment.

2.6 Amoxicillin is practically not metabolized and is excreted mainly unchanged with urine and, to a lesser extent, with bile.

2.7 Amoxicillin 80-TRV, according to the degree of the exposure, belongs to low-hazard substances (hazard class 4 according to GOST 12.1.007-76).

**3. DOSAGE AND INDICATION**

3.1 Amoxicillin 80-TRV is used in piglets, calves and poultry with a therapeutic purpose for colibacteriosis, salmonellosis, pasteurellosis, hemophilia, necrobacteriosis, streptococcosis, clostridiosis, pig erysipelas, actinobacillary pleurativoacillus disease, pseudo-bacilli and other pneumoniae disease bacterial etiology, the causative agents of which are sensitive to amoxicillin.

3.2 The veterinary product is administered orally with water or food, individually or in groups, for 3-5 days in the following doses, in accordance with the table:

Table - Doses of the veterinary product

Animal species	Recommended dose	
	with water	with feed
<b>in groups</b>		
pigs up to 6 months of age	100 g of the veterinary product (80 g of active substance) per 1000 liters of water	100 g of the veterinary product (80 g of active substance) per 1 metric ton of the feed
pigs over 6 months of age	200 g of the veterinary product (160 g of active substance) per 1000 liters of water	200 g of the veterinary product (160 g of active substance) per 1 metric ton of the feed
poultry	100-250 g of the veterinary product (80 g-200 g of active substance) per 1000 l of drinking water	10-20 mg of the veterinary product (8 mg-16 mg of active substance) per 1 kg of body weight
<b>individually</b>		
calves, piglets	15-30 mg of the veterinary product (12-24 mg of active substance) per 1 kg of body weight once a day	
poultry (broiler chickens, turkeys)	10-20 mg of the veterinary product (8 mg-16 mg of active substance) per 1 kg of body weight.	

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, except for cases of individual hypersensitivity to the components of the medicinal product, were not identified. If symptoms of an allergic reaction appear, the veterinary product is discontinued and, if necessary, symptomatic therapy antihistamines and calcium preparations are started. In case of an overdose of the veterinary product in animals, there may be a decrease in appetite, depression, vomiting and diarrhea.

3.5 Contraindications. The use of the veterinary product is contraindicated in case of hypersensitivity to antibiotics of the penicillin group. Must not be used simultaneously with the following antibiotics: macrolides, lincosamides, tetracyclines, sulfonamides, as well as animals with kidney and liver diseases, and cattle with developed cicatricial digestion.

3.6 Must not be used in poultry, whose egg is used as food for humans, replacement chickens less than two weeks before the start of egg-laying, due to the accumulation of amoxicillin in the marketable egg.

3.7 Slaughter of poultry for meat is allowed no earlier than 3 days, and pigs and calves - no earlier than 15 days after the last use 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, 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 (T.A. Soboleva, V.V. Sobolev).

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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	
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