APPROVED
Veterinary Medicinal Product Council
Minutes No. 103 dated September 12, 2019

Summary of Veterinary Product Characteristics
AZITHROMYCIN 10%-TRV

1. GENERAL PRODUCT INFORMATION

1.1 Azithromycin 10%-TRV.

1.2 Azithromycin 10%-TRV is an antibacterial veterinary product, solution for injection, clear solution from colorless to light yellow, without impurities, 1 ml contains 100 mg of azithromycin as an active ingredient and excipients- propylene glycol, benzyl alcohol, water for injection.

1.3 The veterinary product is packed in glass or polymer vials of 10, 20, 30, 50, 100, 200 and 400 ml, hermetically closed with rubber stoppers and tamper resistant aluminum caps. Capping with other caps is allowed, ensuring the container closure integrity.

1.4 Azithromycin 10% -TRV is stored in a dry, dark place at temperatures from plus 5°C to plus 25°C. Shelf life - two years from the date of manufacture, subject to storage conditions. The shelf life once opened is 3 days at a temperature of plus 5°C to plus 25°C.

2. PHARMACOLOGICAL PROPERTIES

2.1 Azithromycin 10% -TRV is a broad-spectrum antibacterial veterinary product.

2.2 Azithromycin is an antibiotic of the macrolide group, the azalide subgroup has a bactericidal effect on gram-positive and gram-negative microorganisms, including: gram-negative - Actinobacillus pleuropneumoniae, Actinobacillus lignieresi, Mannheimia haemolytica, Pasteurella multocida, Haemophilppppella Campocella. , Fusobacterium necrophorum, Salmonella spp., Escherichia coli; gram-positive - Listeria spp., Staphylococcus spp., Streptococcus spp., Clostridium perfringens; and also Chlamydia spp., Mycoplasma bovis and Mycoplasma hyopneumoniae.

2.3 The mechanism of action of azithromycin is associated with inhibition of protein biosynthesis by the ribosomes of bacteria (the formation of peptide bonds between amino acids and the peptide chain is disrupted).

2.4 Azithromycin has a postantibiotic effect - persistent inhibition of the vital activity of bacteria after their short-term contact with an antibacterial veterinary product. The effect is based on irreversible changes in the ribosomes of the microorganism, resulting in a persistent translocation block. Due to this, the general antibacterial effect of the veterinary product is enhanced and prolonged, remaining for the period necessary for the resynthesis of new functional proteins of the microbial cell.

2.5 The veterinary product is well absorbed and quickly distributed in the tissues of the body, reaching high concentrations, many times higher than the concentration in blood plasma. The maximum concentration of the antibiotic in the blood is reached after 30-60 minutes, and the therapeutic concentration remains in the body of animals for up to 72 hours, in the lungs and macrophages for up to 120 hours.

2.6 Azithromycin 10% -TRV is eliminated mainly unchanged with the urine and bile.

2.7 Azithromycin 10% -TRV, according to the degree of exposure, belongs to low-hazard substances (hazard class 4 according to GOST 12.1.007-76).

3. DOSAGE AND INDICATION

3.1 Azithromycin 10% -TRV is used as a treatment for cattle, sheep and pigs in the treatment of bacterial infections caused by microorganisms sensitive to azithromycin: infections of the respiratory system, digestive and genitourinary system, infections of the skin and soft tissues, necrobacteriosis; erysipelas of pigs; spirochetosis; mycoplasma infections; conjunctivitis.

3.2 The veterinary product is administered intramuscularly once a day for 2 days in the following doses, in accordance with the table.

Table – Doses

Animal species	Recommended dose
Cattle	at a dose of 1 ml of the veterinary product per 20-40 kg of animal weight (5 mg of active substance per 1 kg of animal weight), with severe lesions of the lung tissue, repeated injection of the veterinary product is possible after 3-5 days.
Sheep and pigs	at a dose of 1 ml of the veterinary product per 20 kg of animal weight (5 mg of active substance per 1 kg of animal weight)

Repeat the injection if necessary.

3.3 When treating animals weighing more than 300 kg, the dose is divided so that the volume of the veterinary product administered at one point does not exceed 7.5 ml.

3.4 Contraindications. The use of the veterinary product is contraindicated in case of hypersensitivity to the components of the veterinary product, animals with renal and hepatic insufficiency. Must not be used in pregnant animals and animals during lactation.

3.5 Must not be used simultaneously with bactericidal antibiotics, macrolides and amphenicol.

3.6 Animals kill for meat is allowed no earlier than 40 days after the last use of the veterinary product.

The meat of animals forced to be 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, (A.Yu. Finogenov, T.A. Soboleva, E.G. Finogenova).

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