APPROVED
Veterinary Medicinal Product Council
Minutes No. 104 dated October 25, 2019

Summary of Veterinary Product Characteristics
TULATHROMYCIN 10-TRV

1. GENERAL PRODUCT INFORMATION

1.1 Tulathromycin 10-TRV.

1.2 Tulathromycin 10-TRV 10-TRV is an antibacterial veterinary product, solution for injection, colorless transparent solution, without impurities, 1 ml contains 100 mg of tulatromycin 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, 400 ml, hermetically closed with rubber stoppers and tamper resistant aluminum caps. Capping with other types of caps is allowed, ensuring the container closure integrity.

1.4 Tulathromycin 10-TRV is stored according to the requirements of the list B: in a dry, dark place at a temperature from plus 5 ° C to plus 25 ° C.

The shelf life is three years from the date of manufacture, subject to the storage and transportation terms. Once opened the veterinary product is stored for 28 days

2. PHARMACOLOGICAL PROPERTIES

2.1 Tulathromycin 10-TRV is an antibacterial veterinary product of the macrolide group.

2.2 Tulathromycin is a semi-synthetic bacteriostatic antibiotic with a broad spectrum of action against many gram-positive and gram-negative microorganisms, including: *Pasteurella multocida, Mannheimia (Pasteurella) haemolytica, Haemophilus somnus, Haemophilus parasuis parasuis, Mycoplasma hyperemia spp., Neisseria spp.*

2.3 The mechanism of action of tulathromycin is to suppress protein synthesis at the ribosomal level.

2.4 The veterinary product is rapidly absorbed from the injection site and reaches its maximum plasma concentration 30 minutes after administration.

2.5 Tulathromycin accumulates in neutrophils and alveolar macrophages, as a result of which its increased concentration is reached in the lung tissues.

2.6 Tulathromycin is slowly excreted from the body, mainly by the kidneys unchanged. Half-life is about 90 hours

3. DOSAGE AND INDICATION

3.1 Tulathromycin 10-TRV is used in calves and pigs with bacterial respiratory infections (pasteurellosis, hemophillosis, mycoplasmosis), infectious keratoconjunctivitis and other diseases of bacterial etiology, the causative agents of which are sensitive to tulatromycin.

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

Table- doses:

Animal species	**Recommended dose**
cattle	subcutaneously at a dose of 1 ml per 40 kg of live weight (2.5 mg of active substance per 1 kg of live weight)
pigs	intramuscularly in the neck at a dose of 1 ml per 40 kg of live weight (2.5 mg of active substance per 1 kg of live weight)

When administered to farm animals, the dose is divided in such a way that the volume administered at one site does not exceed: 2 ml - for pigs whose body weight exceeds 80 kg; 7.5 ml - for cattle, whose body weight exceeds 300 kg.

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 in animals, the veterinary product is discontinued and, if necessary, symptomatic therapy is started.

3.5 When the therapeutic dose is increased by 3-5 times, cattle and pigs experience anxiety associated with discomfort at the injection site and a slight decrease in appetite. In case of an overdose, symptomatic treatment is performed.

3.6 The use of the veterinary product is contraindicated in case of hypersensitivity to the components of the veterinary product.

3.7 Must not be used in productive animals, whose milk is used for human consumption in connection with the release of tulathromycin in milk, as well as pregnant cows and heifers less than two months before the expected start of lactation (calving) if milk is planned to be used for food purposes.

3.8 Simultaneous use of the veterinary product with other macrolides or lincosamides is not allowed.

3.7 Tulathromycin 10-TRV can be used with emeriostatics.

3.9 Slaughtering of cattle for meet is allowed no earlier than 64 days after the last use of the preparation and of pigs - no earlier than 68 days after the last use of the preparation.

Meat of animals, 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 (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
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