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

Summary of Veterinary Product Characteristics
OXICET-TRV

1. GENERAL PRODUCT INFORMATION

1.1 Oxicet-TRV.

1.2 Oxicet-TRV is an antibacterial veterinary product in the form of a solution for injection, clear liquid from amber to dark brown, a greenish tint is possible, without impurities, 1 ml contains 200 mg of oxytetracycline hydrochloride and 30 mg of ketoprofen as active ingredients and excipients - 1- methyl 2-pyrrolidone, propylene glycol, benzyl alcohol, magnesium oxide, monoethanolamine, water for injection..

1.3 The 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 Oxicet-TRV is stored in a dry, dark place at temperatures from plus 5°C to plus 25°C. Shelf life is 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 Oxicet-TRV is broad-spectrum antibacterial veterinary product.

2.2 Oxytetracycline has a broad spectrum of antibacterial action, inhibits the growth of most gram-positive and gram-negative microorganisms, including:

- gram-positive - *Staphylococcus spp., Streptococcus spp.; Corynebacterium spp., Clostridium spp., Erysipelothrix rhusiopathiae, etc.*;

- gram-negative bacteria - *Escherichia coli, Pasteurella spp., Salmonella spp., Bordetella spp., Actinobacillus spp., Brucella spp*. and etc.;

- as well as *Rickettsia spp., Chlamydia spp., Mycoplasma spp*. protozoa and spirochetes.

It has no effect on Pseudomonas aeruginosa, Proteus.

2.3 The mechanism of action of oxytetracycline is based on the suppression of protein synthesis by the microbial cell (blockade of ribosome function) and blockade of RNA synthesis.

2.4 Ketoprofen is a propionic acid derivative and has a pronounced anti-inflammatory, analgesic and antipyretic effect.

2.5 The mechanism of action of ketoprofen is to suppress the synthesis of prostaglandins as a result of effects on the metabolism of arachidonic acid. The therapeutic effect of ketoprofen is due to its ability to inhibit the synthesis of an enzyme involved in the synthesis of prostaglandins, and to reduce the biosynthesis of prostaglandins directly responsible for the appearance of edema and pain in the focus of inflammation.

2.6 The veterinary product is rapidly absorbed into the bloodstream and penetrates into most organs and tissues of the body. The maximum concentration of the antibiotic in the blood is reached after 30-60 minutes and is maintained at a therapeutic level for 3 days after a single injection of the veterinary product.

2.7 Oxytetracycline is excreted from the body mainly in the urine and partially in feces, in lactating animals - in milk, ketoprofen is excreted from the body mainly in the urine.

2.8 Oxicet-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 Oxicet-TRV is used in

cattle and small cattle with bronchopneumonia, bacterial enteritis (diarrhea), leptospirosis, anaplasmosis, infected wounds, acute metritis, septic mastitis, combined infections, secondary bacterial infections in viral diseases, in small cattle with hoof rot;

pigs with bacterial enteritis (diarrhea, colibacillosis), pneumonia, leptospirosis, atrophic rhinitis, erysipelas, postoperative infections, joint infections, for sows it is suitable for the complex therapy of infectious enteritis (diarrhea in newborn piglets with colibacillosis) and MMA syndrome (metritis-mastitis-agalactia), secondary infections in viral diseases.

3.2 The veterinary product is administered in the following doses, in accordance with the table:

Table - Doses of the veterinary product

Animal species	**Recommended dose**
cattle, small ruminants, pigs	intramuscularly or subcutaneously at a dose of 1 ml of the veterinary product per 10 kg of animal weight (20 mg of oxytetracycline and 3 mg of ketoprofen per 1 kg of animal weight) once a day
In case of serious diseases, the veterinary product is re-administered: - cattle - after 72 hours; - pigs, small ruminants - after 48 hours	

3.3 Before use, the preparation must be thoroughly shaken until a homogeneous solution is formed. Slight cloudiness of the product does not change its effect.

3.4 In view of the possible painful reaction, the maximum volume of the veterinary product for administration in one site should not exceed: for cattle - 10 ml; for pigs and sheep - 5 ml; for small animals - 1-4 ml.

3.5 Adverse effects, with the exception of cases of individual hypersensitivity to the components of the medicinal product, were not identified. If symptoms of an allergic reaction appear in animals, the veterinary product is discontinued and, if necessary, symptomatic therapy is prescribed.

3.6 Contraindications. The use of the veterinary product is contraindicated in case of hypersensitivity to antibiotics of the tetracycline group and ketoprofen. It must not be used in animals with severe renal and hepatic insufficiency.

3.7 Concomitant use of the veterinary product with other bactericidal antimicrobial veterinary products or with infusion solutions, with concomitant vaccinations is not allowed, due to the possible decrease in the antibacterial effect of oxytetracycline.

3.8 Slaughter of animals for meat is allowed no earlier than 28 days after the last administration 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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12.09.2019 Minutes No. 103