APPROVED
Veterinary Medicinal Product Council
dated March 14, 2019 Minutes No. 100

Summary of Veterinary Product Characteristics

ENRODGECT 100

1. GENERAL PRODUCT INFORMATION

1.1 Enrodgect 100.
1.2 Enrodgect 100 - antibacterial veterinary medicinal product in the form of a solution for injection, clear from light yellow to yellow solution, each ml contains 100 mg of enrofloxacin as an active substance and excipients - potassium hydroxide, benzyl alcohol, water for injection.
1.3 The veterinary medicinal product is packed in glass vials of appropriate capacity of 10, 20, 30, 50, 100, 200 and 400 ml, hermetically sealed with rubber stoppers and reinforced with flip-off screw tamper proof caps.
1.4 Enrodgect 100 is stored in a dry, dark place at a temperature from + 5 ° C to + 25 ° C. Shelf life is two years from the date of manufacture, subject to storage conditions. After opening the vial, the veterinary medicinal product is stored for 3 days at a temperature from + 5 ° C to +25 ° C.

2. PHARMACOLOGICAL PROPERTIES

2.1 Enrofloxacin, an active substance, belongs to the group of fluoroquinolones. The mechanism of action of enrofloxacin is based on blocking the synthesis of DNA gyrase, which leads to disruption of DNA synthesis and inhibits the formation of malic acid in microorganisms.
2.2 Enrofloxacin has a broad spectrum of action against gram-positive and gram-negative bacteria, incl. *Escherichia coli, Salmonella spp., Pasteurella spp., Pseudomonas aeruginosa, Haemophilus spp., Bordetella spp., Staphylococcus spp., Streptococcus spp., Clostridium spp., Leptospira spp., Proteus spp.*, and also *Mycoplasma spp*.
2.3 The veterinary medicinal product is well and rapidly absorbed in the gastrointestinal tract and penetrates into all organs and tissues of animals. The maximum concentration of the veterinary medicinal product in the blood is reached within 0.5 - 1 hour after administration and remains for 4 - 6 hours, and the therapeutic concentration - for 24 hours. The veterinary medicinal product practically does not undergo biotransformation in the body.
2.4 Enrofloxacin is excreted unchanged from the body, mainly in urine and faeces.

3. INDICATIONS FOR USE

3.1 Enrodgect 100 is used as a therapeutic agent for treatment colibacillosis, salmonellosis, pasteurellosis, pseudomonosis, clostridiosis, mycoplasmosis (calves, lambs, pigs), bordetellosis, MMA syndrome (mastitis-metritis-agalactia syndrome) in pigs and other infectious diseases, pathogens are sensitive to enrofloxacin.
3.2 The veterinary medicinal product is administered subcutaneously or intramuscularly once a day for 3-5 days in the following doses, in accordance with the table:
Table - Veterinary medicinal product dosage

Class of Stock	**Recommended dose**
Calves and lambs	Subcutaneously 0.5 ml of the veterinary product per 10 kg of animal weight
Pigs	Intramuscularly 0.5 ml of the veterinary product per 10 kg of animal weight

3.3Due to the possible pain reaction, the maximum volume of the veterinary medicinal product at injection site should not exceed 2-3 ml for cattle, 1 ml for small stock.
3.4 Adverse reactions, with the exception of cases of individual hypersensitivity to the components of the veterinary medicinal product, have not been identified. In case of symptoms of an allergic reaction in animals, the veterinary medicinal product is discontinued and, if necessary, symptomatic therapy is prescribed.
3.5 Contraindications. The use of the veterinary medicinal product is contraindicated in case of hypersensitivity to the components of the veterinary medicinal product.
3.6 The veterinary medicinal product should not be used simultaneously with antibiotics of the tetracyclines and macrolides groups, non-steroidal anti-inflammatory veterinary medicinal products, as well as hypersensitivity to fluoroquinolones.
3.7 Slaughtering of animals for human consumption is allowed no earlier than 14 days after the last use of the veterinary medicinal product.
Meat of animals and poultry, forcedly killed before the expiration of the specified period, can be used as feed for carnivores

4. PREVENTIVE MEASURES

4.1 Generally accepted personal hygiene measures and safety rules should be observed when working with this veterinary medicinal product.

5 CLAIMING PROCEDURE

5.1 In case of complications after the use of the veterinary medicinal 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 medicinal product in accordance with the instructions. After the confirmation of a veterinary medicinal 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 medicinal 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. for TrionisVet, 141092, Russia, Moscow region, Korolev, md. Yubileynyj, st. Lesnaya, 14, office 5.
The Summary of Veterinary Product Characteristics was developed by the employees of TrionisVet, LLC (A.Yu. Finogenov, T.A. Soboleva, E.G. Finogenova).

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Veterinary Medicinal Product Council
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Chairman [*Signature*]
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