APPROVED
Veterinary Medicinal Product Council
Minutes No. 110 dated September 10, 2020

Summary of Veterinary Product Characteristics
TRIVIRON FORTE-TRV

1. GENERAL PRODUCT INFORMATION

1.1 Triviron forte-TRV.

1.2 Triviron forte-TRV is an antiviral veterinary drug, oral solution, clear solution from light yellow to yellow, 1.0 ml contains 30.0 mg of aRNase (1.5-bis- [N.N- 1- (4- tetradecyl) diazo1-1- abicyclo [2.2.2] octyl] pentane tetrobromide), and excipients: propylene glycol and lactic acid.

1.3 The veterinary drug is packed in polymer container of 100.0 ± 5.0 ml, 250.0 ± 10.0 ml, 500.0 ± 15.0 ml, 1000.0 ± 50.0 ml with screw caps.

1.4 Triviron forte-TRV is stored according to the requirements of the list B: in a dry, dark place at a temperature from plus 4° C to plus 25 ° C. The shelf life is two years from the date of manufacture, subject to the storage terms. Once opened the veterinary drug is stored for 28 days.

2. PHARMACOLOGICAL PROPERTIES

2.1 The veterinary drug has a pronounced effect on RNA-containing viruses of the families *Paramyxoviridae, Coronaviridae, Arenaviridae, Retroviridae, Picornaviridae, Birnaviridae, Orthomyxoviridae,* etc.

2.2 The mechanism of action is based on the damage of RNA viral particles using a low molecular weight artificial ribonuclease. High stability to physical and chemical factors, as well as the small size of artificial RNase in comparison with protein molecules, provide high efficiency of antiviral therapy. The small molecular weight of the compound increases the efficiency of penetration of synthetic ribonuclease into the virus capsid and high chemical and temperature stability provides the possibility of oral administration of the antiviral veterinary drug.

2.3 The veterinary drug is not toxic, no contraindications were found.

2.4 The veterinary drug according to the degree of exposure belongs to moderate-hazard substances (hazard class 3 according to GOST 12.1.007-76).

3. DOSAGE AND INDICATION

3.1 Triviron forte-TRV is used for therapeutic and prophylactic purposes in animals and poultry with infections caused by RNA viruses:

- poultry - infectious bronchitis of chickens, infectious bursal disease, avian influenza, viral arthritis in poultry, Newcastle disease, pneumovirus in poultry, paramyxoviruses in poultry, infectious encephalomyelitis in poultry, coronavirus enteritis of turkeys, astroviral infections in poultry, hepatitis of ducks, viral hepatitis of turkeys, viral nephritis of turkeys and other infections caused by RNA genomic viruses sensitive to the veterinary drug;
- calves - rotavirus enteritis, coronavirus enteritis, parainfluenza-3, respiratory syncytial infection, and other infections caused by RNA genomic viruses sensitive to the veterinary drug.

3.2 The veterinary drug is administered

3.2.1 Poultry:

- for prophylactic purposes at the dose of 0.00125-0.0025 ml of the veterinary drug per 1 kg of body weight. The veterinary drug is introduced into the drinking system through a medicator (1-2% input), having previously dissolved it in a volume of water (corresponds to the volume of the medicator's stock solution), which the poultry can drink within 6-8 hours. The course is 2-10 days.

- for therapeutic purposes at the dose of 0.0025-0.005 ml of the veterinary drug per 1 kg of body weight. The veterinary drug is introduced into the drinking system through a medicator (1-2% input), having previously dissolved it in a volume of water (corresponds to the volume of the medicator's stock solution), which the poultry can drink within 4-6 hours. The course is 2-10 days.

3.2.2 Cattle:

- for prophylactic purposes at the dose of 0.05 ml of the veterinary drug per 1 kg of body weight. Before drinking, the veterinary drug must be diluted in drinking water in a ratio of 1: 1000. The course is 2-10 days.

- for therapeutic purposes at the dose of 0.1 ml of the veterinary drug per 1 kg of body weight. Before drinking, the veterinary drug must be diluted in drinking water in a ratio of 1: 1000. The course is 2-10 days.

It is forbidden to drink the veterinary drug in its pure form to animals and poultry!

3.3 When diluting, the veterinary drug is added to water in a thin stream (to avoid the formation of a precipitate) with vigorous stirring.

3.4 There were no adverse effects and complications.

3.5 It is not recommended to use the veterinary drug simultaneously with live vaccines based on attenuated RNA-containing strains of viruses, such as Gumboro disease virus, Newcastle disease virus, chicken infectious bronchitis virus, encephalomyelitis virus, etc.

3.6 Slaughter of animals for meat, as well as the use of products during the use of the veterinary drug is allowed without restrictions.

4. PREVENTIVE MEASURES

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

5 CLAIMING PROCEDURE

5.1 In case of complications after the use of the veterinary drug, 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 drug in accordance with the instructions. After the confirmation of a veterinary drug 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 drug 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).

[Stamp]:

Department of Veterinary and Food Control of the Ministry of Agriculture and Food of the Republic of Belarus
Veterinary Medicinal Product Council
Approved
Chairman [*Signature*]
Secretary [*Signature*]
Expert [*Signature*]
10.09.2020 Minutes No. 110