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

Summary of Veterinary Product Characteristics

Ferrum 20/B12-TRV

1. GENERAL PRODUCT INFORMATION

1.1 Ferrum 20 / B12-TRV.

1.2 Ferrum 20 / B12-TRV- Solution for injection, slightly viscous solution, red-brown or dark brown, without impurities, dissolved sediment is allowed. Each ml of the veterinary product contains 200 mg of iron (in the form of iron dextran), 200 μg of cyanocobalamin (vitamin B12) and excipient – water for injection.

1.3 The veterinary product is packed in glass or polymer bottles with a capacity of 10, 20, 30, 50, 100, 200 and 400 ml, hermetically sealed with rubber stoppers and reinforced with aluminium caps with tamper-evident clips. Capping with other stoppers is allowed, ensuring the tightness of the package.

1.4 The veterinary product 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 bottle, the veterinary product is stored for 3 days at a temperature from 5 ° C to 25 ° C.

2. PHARMACOLOGICAL PROPERTIES

2.1 Iron 20 / B12-TPV belongs to the group of anti-anaemic agents, stimulants of hematopoiesis, as well as to the group of veterinary products for the metabolic care improvement.

2.2 The veterinary product is used for prevention and treatment of iron deficiency anaemia caused by iron and cyanocobalamin deficiency in piglets and calves.

2.3 Iron is part of a number of tissue enzymes (cytochromes, cytochrome oxidases, peroxidases, etc.). These enzymes are catalysts of cellular respiration, stimulate oxidative reactions, increase the metabolic and phagocytic activity of leukocytes, increase the efficiency of intracellular digestion and barrier properties of the skin, and contribute the general resistance of the organism.

From the injection site, iron gradually enters the blood stream and binds to a specific blood plasma protein - transferrin. Each transferrin molecule binds two trivalent iron. The iron-transferrin complex is deposited in the liver, spleen, bone marrow and is gradually consumed for the synthesis of haemoglobin, myoglobin.

2.4 Cyanocobalamin is converted in the body to adenosylcobalamin (cobamamide), which is the active form of vitamin B12. Cyanocobalamin has high biological activity, is a growth factor, is necessary for normal haematopoiesis and maturation of erythrocytes, participates in the synthesis of methyl groups and in the formation of choline, methionine, creatine, nucleic acids. It accumulates in the liver, is excreted from the body mainly by kidneys.

2.5 The apparent elimination half-life of iron from blood plasma is five hours. A small amount of iron is excreted in the urine. Dextran is metabolized and excreted by kidneys.

2.6 The veterinary product, according to the exposure degree refers to low-hazard substances (hazard class 4 according to GOST 12.1.007-76).

3. INDICATIONS FOR USE

3.1 The veterinary product is used for therapeutic and prophylactic purposes in piglets, calves, pregnant cows and heifers, farrowing sows with anaemia.

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

Table - Doses of the veterinary product

Class of Stock	**Recommended dose**

Piglets	1 ml intramuscularly on the 3rd day of life
Calves	2-4 ml subcutaneously in the first week of life
Pregnant cows and heifers	Inject once 10.0 ml per animal subcutaneously 25-35 days before calving
Farrowing sows	Inject once 5.0 ml per animal intramuscularly 20-25 days before farrowing

3.3 Adverse reactions, except of cases of individual hypersensitivity to the components of the veterinary product, have not been identified. A slight swelling of the tissues may occur at the injection site, which disappears within 2-3 days.

3.4 The use of the veterinary product is contraindicated in animals in cases of hypersensitivity to any of the excipients, as well as:

- to animals suspected to suffer from deficiency of vitamin E and/or selenium (if the deficiency is detected by a biochemical blood test or there are typical clinical signs);
- diarrhoea;
- in combination with tetracyclines.

Simultaneous use of the veterinary product with antiparasitic agents is not allowed.

3.5 Slaughtering of animals for human consumption 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 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, Limited Liability Company, 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).

[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*]
25/10/2019. Minutes No. 104