

SULF granules

PACKAGE LEAFLET

for use of Sulf granules for treatment of animals at the diseases of bacterial etiology

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(Development organization: NVTs Agrovetzashchita Ltd., bld. 1, 1, Kolskaia St., Moscow, 129329 Russia)

I. General

Trade name: Sulf granules (Granulae Sulfum).

International nonproprietary names of the drug product: trimethoprim, sulfadiazine.

Dosage form: granules for oral administration.

Sulf granules contain the following active ingredients in 1 g – trimethoprim: 0.02 g and sulfadiazine: 0.1 g, as well as the excipients like potato starch and lactose.

Appearance: the drug product represents granules of white to greyish color.

The shelf life of the drug product shall be 3 years from the manufacturing date at compliance with the recommended storage conditions. Taking of Sulf granules after the expiration date is prohibited.

The drug product is packaged in packages of multilayer paper of 0.2, 0.5, 1, 5 and 20 kg; and polymeric cans with lids of 0.1, 0.2, 0.5 and 1 kg with a measuring spoon.

Sulf granules are stored tightly closed in the packaging provided by the manufacturer, in the place protected from direct sunlight and moisture, separately from foodstuff and fodders, at the temperatures from 0°C to 25°C. Sulf granules must be kept out of reach of children.

Unused drug product should be disposed in accordance with legal requirements.

Available without a veterinarian's prescription.

II. Pharmacological properties

Sulf granules belong to the group of compound sulfanilamide antibacterial drug products.

Trimethoprim and sulfadiazine included into the composition of Sulf granules enhance the effect of each other by means of consequent action exerted on the metabolism of n-aminobenzoic and folic acids within the bacterial cell providing for a broad range of antibacterial effect. The drug product is active against gram-positive and gram-negative microorganisms including *E.coli*, *Clostridium spp.*, *Salmonella spp.*, *Proteus spp.*, *Bacillus anthracis*, *Pasteurella spp.*, *Haemophilus spp.*, *Vibrio spp.*, *Staphylococcus spp.*, *Streptococcus spp.*, *Shigella spp.*, *Corynebacterium spp.*, *Klebsiella spp.*, *Fusobacterium spp.*, *Bordetella spp.* and *Brucella spp.*

At oral administration of the drug product, its active ingredients are fast absorbed by the gastrointestinal tract and penetrate into most parts and tissues of the animal body attaining maximum concentrations in the blood serum after 3 to 4 hours and maintaining the therapeutic level during not less than 12 hours; the active ingredients are excreted from the body primarily with the urine or partially with milk at the lactating animals.

In terms of the effect upon the animal body Sulf granules can be referred to moderately hazardous substances (hazard class 3 according to GOST 12.1.007-

76) and well tolerated by the animals if taken in recommended dosages.

III. Indications

Sulf granules are administered to young animals of bovine, sheep and goats, foals, porcine, dogs, cats and fur-bearing animals for the treatment purposes at bacterial infections of respiratory system, gastrointestinal tract, urogenital system, skin, wound infections, pasteurellosis, salmonellosis and other diseases, the pathogens of which are sensitive to sulfanilamide drug products. Contraindications for taking the drug product Sulf granules include increased sensitivity of the animal to sulfadiazines; hematopoietic function disorders, dysfunctions of liver and kidneys.

Sulf granules are taken as oral administration mixed with fodder or water used for watering (with milk) in the daily dosage of 1 g of the drug product per 4 kg of the animal body weight in two takings with the interval of 12 hours. Duration of treatment comprises 5 to 7 days.

Disorders of kidneys and the gastrointestinal tract (dysbacteriosis) are possible at overdosing or exceeding the prescribed course of treatment. In this case taking of the drug product must be stopped and symptomatic treatment drug products (alkali fluids, vitamins and probiotics) should be administered to the animal.

No particularities of action of Sulf granules at first use and termination of use are revealed.

Taking of this drug product by pregnant or lactating animals is not allowed.

Non-compliance with the recommended scheme for proper use of the drug product must be avoided because it might result in decreasing of the therapeutic efficiency. In the event of missed taking of the dose the drug product must be taken as soon as possible in the prescribed dosage and under the same treatment scheme.

At taking of Sulf granules in accordance with this package leaflet no side effects and complications are observed, as a rule, at the animals. In the cases of individual sensitivity of an animal to the ingredients of the drug product and occurrence of allergic reactions taking of the drug product must be stopped.

Sulf granules must not be taken simultaneously with the drug products of the n-aminobenzoic acid group (novocain, procaine, anaesthesin, benzocaine).

Slaughter of animals for meat is allowed not earlier than in 9 days after the last taking of the drug product. Meat of the animals brought to an involuntary slaughter before expiration of the abovementioned term may be used for feeding of fur-bearing animals.

IV. Personal preventive measures

The requirements set to personal hygiene and labor

safety and health regulations imposed on handling drug products must be complied with while handling Sulf granules. Smoking, drinking and having meals is prohibited while handling the drug product. After handling the drug product wash your hands with soap and lukewarm water. People with hypersensitivity to the

ingredients of the drug product must avoid direct contacting with Sulf granules. In the event of occurrence of allergic reactions and/or at incidental swallowing of the drug product consult the physician immediately (take away with you this package leaflet or the drug product label).

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/AVZ

animal health/

Name and address of the production site of the manufacturer of the drug product for veterinary use:

AVZ S-P LTD., 1, Tsentralnaia str., Sergiyev Posad, Moscow region, 141305 Russia.

Name and address of the organization authorized by the marketing authorization holder or owner of the drug product to accept claims from the consumers: AVZ S-P LTD., 1, Tsentralnaia str., Sergiyev Posad, Moscow region, 141305 Russia.

24-hour hotline: 8-800-700-19-93 (toll free in Russia).

See information on product conformity assessment at: **www.vetmag.ru**.