

Doxyor 10%

PACKAGE LEAFLET

for use of Doxyor 10% for treatment of porcine and domestic fowl at the diseases of bacterial etiology

Approved by: N.A. Vlasov, the Deputy Head of the Federal Service for Veterinary and Phytosanitary Surveillance

(Development organization: Areal Medical LLC, 1, Kolskaia St., Moscow, 129329 Russia).

I. General

Trade name: Doxyor 10%.

International nonproprietary name: doxycycline.

Dosage form: solution for oral administration.

Doxyor 10% contains the following active ingredient in 1 ml of the solution: doxycycline in the form of hyclate – 100 mg, as well as the excipients like 1-methyl-2-pyrrolidone and propylene glycol.

Appearance: Doxyor 10% represents a transparent fluid of yellow and brown 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 the drug product after the expiration date is prohibited.

The drug product is packaged in dark glass vials of 100 ml of appropriate capacity sealed with rubber stoppers and aluminum caps; into the polymeric vials with screw plastic caps, 0.5 and 1 l polymeric bottles and polymeric canisters of 5 and 10 l of appropriate capacity sealed with screw plastic lids with the first opening control ring. Every consumer package contains the package leaflet for use of the drug product.

Doxyor 10% is stored tightly closed in the packaging provided by the manufacturer, in the place protected from direct sunlight, separately from foodstuff and fodders, at the temperatures from 0°C to 25°C.

Doxyor 10% must be kept out of reach of children.

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

Doxyor 10% is available without a veterinarian's prescription.

II. Pharmacological properties

Doxyor 10% belongs to antibacterial drug products of the tetracycline group. Doxycycline included into the composition of the drug product is a semi-synthetic antibiotic of the group of tetracyclines; possessing a broad range of antibacterial effect, it is active against the following gram-positive and gram-negative microorganisms of some protozoa along with the pathogens of mycoplasmoses, including *Escherichia coli*, *Haemophilus spp.*, *Pasteurella spp.*, *Salmonella spp.*, *Staphylococcus spp.*, *Streptococcus spp.*, *Clostridium spp.*, *Chlamydia spp.*, *Rickettsiae spp.*, *Klebsiella spp.*, *Listeria spp.*, as well as *Mycoplasma spp.* Mechanism of the bacteriostatic effect of doxycycline is based on suppression of activity of the enzymes serving as catalysts for bonding of aminoacyl-RNA with the ribosome acceptors that results in blocking of the interaction between aminoacyl transport RNA and matrix RNA and breaching the protein synthesis in the bacterial cell.

After oral administration of the drug product, doxycycline is well absorbed by the gastrointestinal tract and penetrates into most parts and tissues of the animal body attaining maximum concentrations in blood plasma in 2 to 4 hours after administration and maintains at the therapeutic level during 18 to 24 hours. Doxycycline is excreted from the body primarily in with gall in the form of non-active complexes.

In terms of the effect upon the animal body Doxyor 10% can be referred to low hazardous substances (hazard class 4 according to GOST 12.1.007-76).

III. Indications

Doxyor 10% is administered to porcine and domestic fowl for treatment and preventive treatment purposes at colibacteriosis, pasteurellosis, salmonellosis, staphylococcosis, chronic respiratory diseases mycoplasmosis and other infections, the pathogens of which are sensitive to doxycycline.

Contraindication for taking of Doxyor 10% includes increased sensitivity of the animal to the ingredients of the drug product.

It is prohibited to give the drug product to the animals with expressed hepatic and renal insufficiencies as well as to laying hens and rearing flock of chicken older than 16 weeks due to accumulation of doxycycline in the eggs. Doxyor 10% is administered orally both individually and in groups with water for drinking in the following dosages:

- porcine – 1 ml per 10 kg of animal body weight (equivalent to 10 mg of doxycycline per 1 kg of animal body weight) once daily during 5 days

- domestic fowl – 0,5-1,0 ml per 1 l of drinking water (equivalent to 50-100 mg of doxycycline per 1 l of water) during 3 to 5 days.

During the treatment period porcine and domestic fowl must receive solely the water containing the drug product. Solution of the drug product is prepared on a daily basis in the amount calculated for daily consumption of water by animals and birds.

Gastrointestinal tract dysfunction and decreased consumption of fodder may be observed at the animal in the cases of overdosing of the drug product.

No particularities of action of Doxyor 10% at its first use and termination of use are revealed.

Taking of the drug product by pregnant and lactating sows is prohibited. At taking the drug products of the group of tetracycline discoloration of tooth enamel could be observed in young animals in the period of teeth formation and growing. 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. At missing of one dosage taking of the drug product must be renewed as soon as possible in the prescribed dosage and under the same treatment schedule. No side effects and complications are observed, as a rule, while taking Doxyor 10% in compliance with this package leaflet. In the cases of increased sensitivity of the

animal to tetracyclines and occurrence of allergic reactions taking of the drug product must be stopped and antihistamines or symptomatic treatment drug products should be administered.

Taking of Doxyor 10% simultaneously with myorelaxants, bactericide antibiotics, mineral additives and drug products containing salts of calcium, magnesium, iron and aluminum, is not allowed (due to possible decreasing of absorption of the antibiotic).

Slaughter of porcine and domestic fowl for meat is allowed not earlier than in 14 days after the last taking of Doxyor 10%. Meat of porcine and domestic fowl 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 Doxyor 10%. 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 Doxyor 10%. It is prohibited to use empty package where the drug product has been contained for household purposes – the packages must be disposed of with solid waste.

At incidental contact of the drug product with skin it should be immediately washed out with soap and water; at contact with the eyes - rinse thoroughly with plenty of water during several minutes. In the event of occurrence of allergic reactions or at incidental swallowing of the drug product consult the physician immediately (take away with you this package leaflet or the drug product label).

/AVZ

animal health/

Marketing Authorisation No.: in RUSSIA 77-3-5.19-4447 No. IIBP-3-32.13/02995 dated 04.04.2019

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.