

**FLORFENICOL 10%
oral**

PACKAGE LEAFLET

**for use of the drug product Florfenicol 10% oral
for treatment of porcine and domestic fowl at the diseases of bacterial
and mycoplasma 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: Florfenicol 10% oral.

International nonproprietary name: florfenicol.

Dosage form: solution for oral administration.

Florfenicol 10% oral contains in 1 ml 100 mg florfenicol as the active ingredient, and 1-metyl-2-pyrrolidone and propylene glycol as the excipients.

Appearance: Florfenicol 10% oral represents a transparent fluid of colorless to light yellow color.

The shelf life of Florfenicol 10% oral shall be 2 years from the manufacturing date at compliance with the recommended storage conditions in the closed packaging provided by the manufacturer and not more than 30 days after opening of primary package. Taking of the drug product after the expiration date is prohibited.

The drug product is packaged in glass vials of 100 ml sealed with rubber stoppers and aluminum caps; into the 100 and 250 ml polymeric vials, 0.5 and 1 l bottles of appropriate capacity and polymeric canisters of 2,5 and 5 l sealed with screw plastic lids with the first opening control ring. Every consumer package contains the package leaflet for use of the drug product.

Florfenicol 10% oral 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.

Keep 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

Florfenicol 10% oral belongs to antibacterial drug products of the fenicol group.

Florfenicol included into the composition of the drug product is a derivative of thiamphenicol, in the molecule of which the hydroxyl group is substituted by the atom of fluorine.

Florfenicol exerts bacteriostatic effect with regards to gram-positive and gram-negative microorganisms: *Escherichia coli*, *Salmonella* spp., *Staphylococcus* spp., *Streptococcus* spp., *Pasteurella multocida*, *Actinobacillus pleuropneumoniae*, *Ornitobacterium rhinotracheale*, *Haemophilus* spp., *Proteus* spp., *Enterobacter* spp., *Shigella* spp., *Klebsiella* spp., *Bordetella* spp., and the mycoplasma *Mycoplasma* spp. Active against the bacteria producing acetyl transferase and are resistant to chloramphenicol.

Florfenicol is bonded with the 70-S ribosome subunit in the bacterial cell protoplasm, where it blocks action of the peptidyl transferase ferment that results in suppression of synthesis of the protein sensitive bacteria.

After oral administration florfenicol is fast absorbed by the gastrointestinal tract and penetrates into most parts and tissues of the animal body. Therapeutic concentration of the antibiotic is attained in the blood of domestic fowl and porcine in 1 to 1.5 hours and maintained in the body at the therapeutic level during 24 hours after taking of the drug product. Florfenicol is excreted from the body both in the unchanged form and in the form of metabolites primarily with feces; and also with eggs at the egg laying domestic fowl.

In terms of the effect upon the animal body Florfenicol 10% oral can be referred to moderate hazardous substances (hazard class 3 according to GOST 12.1.007-76).

III. Indications

Florfenicol 10% oral is administered:

– to porcine for treatment of the diseases of respiratory system of bacterial etiology: pleuropneumonia caused by *Actinobacillus pleuropneumoniae*, *Haemophilus parasuis*, atrophic rhinitis caused by *Pasteurella multocida*, *Bordetella bronchiseptica*, as well as other diseases in porcine of bacterial etiology caused by microorganisms sensitive to florfenicol, and other secondary bacterial infections;

– to domestic fowl for treatment of colibacteriosis, pastereullosis, diseases of respiratory system of birds of bacterial etiology, including those caused by *Ornitobacterium rhinotracheale*, staphylococcosis and as well as other inflectional diseases caused by the microorganisms sensitive to florfenicol, and other secondary bacterial infections.

It is prohibited to give the drug product to breeding boars, laying hens and rearing flock of chicken less than in 2 weeks before starting laying of eggs due to accumulation of florfenicol in the eggs. This drug product should not be taken in the cases of increased individual sensitivity to the ingredients of the drug product.

Florfenicol 10% oral is administered to porcine individually or in groups with the water for drinking in the daily dosage of 5 ml of the drug product per 100 kg of the animal body weight (corresponding to 5 mg of florfenicol per 1 kg of the animal body weight) during 7 days.

For the domestic fowl the drug product is given in groups with water for drinking in the following daily dosage: chicken under 4 weeks of age – 100 ml of the drug product per 100 l of water; domestic fowl of other age categories – 200 ml of the drug product per 100 l of water (that corresponds to 20 mg of florfenicol per 1 kg of the fowl weight) during 3 days, and at salmonellosis and combined infections – during 5 days.

At taking the drug product in groups, porcine and

domestic fowl must receive solely the water containing the drug product. In the cases when it is not possible daily dosage of the drug product must be divided in 2 equal parts and given with water at the interval of 12 hours.

Excitation followed by suppression, rapid breathing and increased heart rate and mucosa cyanosis can be observed at the animals in the events of overdosing at taking of the drug product. Symptomatic treatment is recommended.

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

It is prohibited to give this drug product to pigs weighing less than 2 kg, and to pregnant and lactating sows.

At missing of one or several dosages taking of the drug product must be renewed as soon as possible in the same prescribed dosage and under the same treatment schedule.

No side effects and complications are observed, as a rule, while taking Florfenicol 10% oral in compliance with this package leaflet. Discoloration of feces, diarrhea, reddening and swelling of the perianal domain are possible in porcine. The above symptoms disappear spontaneously after termination of taking of the drug product.

In the cases of occurrence of allergic reactions taking of the drug product must be stopped and antihistamines and, if necessary, symptomatic treatment should be administered.

Taking of Florfenicol 10% oral is not allowed

simultaneously with thiamphenicol and chloramphenicol, antibiotics of the penicillin group, cephalosporins and fluoroquinolones.

Slaughter of porcine for meat is allowed not earlier than in 6 days and domestic fowl – not earlier than in 2 days after the last taking of Florfenicol 10% oral. Meat of the porcine and domestic fowl brought to an involuntary slaughter before expiration of the abovementioned term may be used for feeding of carnivorous animals.

IV. Contraindications

Do not use in breeding pigs, Do not use in layers producing eggs for human consumption.

V. 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 Florfenicol 10% oral. After handling the drug product wash your hands with soap and lukewarm water. At incidental contact of the drug product with skin or eye mucosa rinse thoroughly with plenty of water. People with hypersensitivity to the ingredients of the drug product must avoid direct contacting with Florfenicol 10% oral. 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. 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).

Marketing Authorisation No.: in Russia 77-3-14.18-4343 No. IIBP-3-29.13/02983 dated 14.01.2019

/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.