Leaflet and Label

For Veterinary Use Only

FLORVİL AQUA

Oral Powder / Veterinary Medicated Premix

Veterinary Systemic Antibacterial

COMPOSITION

It is a white cream colored powder containing 500 mg florfenicol per kg.

PHARMACOLOGICAL PROPERTIES

Florfenicol included in the FLORVİL AQUA Oral Powder is a monohydrate derivative of florfenicol thiamfenicol that it is differentiated from chloramphenicol as it contains p-methyl sulphonyl group instead p-nitro group. Florfenicol has wider spectrum in comparison with thiamfenicol and chloramfenicol. The higher efficiency of florfenicol is based on the inhibition of bacterial enzymatic acetylation by the fluorine replacing the 3rd carbon group in the hydroxyl group. It has bactericide and bacteriostatic effects based on inhibition of protein synthesis in bacterial ribosom.

Effect on bacteria is as follows;

It has good effect on gram-positive aerobes (*Bacillus spp., Corynebacterium spp.*, *Erysipelothrix rhusopathiae, Listeria monocytogenes* and *Streptococcus spp.*), Gram-negative bacteria (*Flavobacter spp., Cytophaga spp.,Vibrio spp., Flexibacter spp., Pseudomonas spp., Aeromonas spp., Actinobacillus spp., Bordetella spp., Francisella tularensis, Haemophilus spp., Pasteurella multocida, Yersinia spp., Campylobacter fetus, Borrelia spp*. and *Leptospira spp.*), anaerobes (*Actinomyces spp., Fusobacterium spp*.) and *Mycoplasma spp., Chlamydia spp., Ehrlichia spp*., *Cooxiella burnetti* and *Anaplasma*.

In fish, florfenicol is rapidly and efficiently absorbed via oral route (in fishes living at water with temperature of 5-15 °C). It is distributed to all body tissues and organs of fish (rate of 96.5 percent). Drug concentrations are similar in muscle, blood and serum, but lower concentrations are observed in fatty tissues and central nervous system. Twenty five percent of the drug and its metabolite in the serum are fed to the brain. Peak serum concentration, 4 mcg/L, is reached in 10.3 hours at dose of 10 mg/kg. Half elimination time is 12.2 hours. It is rapidly metabolized and a part of the dose is converted to amine metabolite of florfenicol and excreted. Elimination rate (total clearance) is 1.4 ml/min/kg.

In salmon fish, florfenicol is rapidly metabolized at water temperature of 8.5-11.5 °C and the most common metabolite is florfenicol amine. When 10 mg/kg dose of oral florfenicol is administered to fishes at water temperature of for eliminating *Aeromonas salmonicida, Vibrio anguillarum* and *V. Salmonicida*, it is reported that minimum inhibitory concentration in plasma is 0.8 mcg/mL.

AREA OF USE / INDICATIONS

FLORVİL AQUA Oral Powder/Veterinary Medicated Premix is effective against many gram positive and gram negative bacteria causing diseases primarily in fresh water fishes (trout, salmon, carp) and sea water fishes (sea bream, sea bass, trout). It is used for treatment of bacterial infections, such as furunculosis (*Aeromonas salmonicida*), vibriosis (*Vibrio anguillarum*), Yersiniosis (*Yersinia ruckerii*), bacterial hemorrhagic septicemia (*Aeromonas hydrophila, Pseudomonas spp.*), columnaris disease (*Flexibacter columnaris*), streptococcal infections (β hemolytic and non-hemolytic *Streptococcus spp.*), cold water vibriosis (*Vibrio salmonicida*), cold water disease (*Cytophaga psycrophila*), winter disease (*Pseudomonas anguiliseptica*), Edwardsiellosis (*Edwersiella ictaluri, Edweersiella tarda*), pasteurellosis

(*Photobacterium damsela subsp. piscidia*) ve marine flexibacteriosis (*Tenacibaculum maritimum*), in cultured fishes.

USAGE AND DOSAGE

FLORVİL AQUA is orally administered by mixing product with fish food.

Pharmacological dose: It is administered mixing with fish food, should dose of active ingredient is 10 mg/kg body weight.

Practical dose: It is administered as oral powder mixed with fish food at dose of 0.02 g/kg body weight. Treatment is continued for 10 days.

Ratio of Fis Food (Acc. To Body weight	Amount of FLORVİL Aqua added to 1 Ton of fish food	Amount of drug used for 10-day treatment
%0,5	4 kg	20,0 kg
%1,0	2 kg	10,0 kg
%2,0	1 kg	5,00 kg

Preparation of Drug-Added Fish Food:

Previously scaled amount of FLORVİL AQUA is added to mixer of fish food blender (they should be dry, clean and sensitive) and oil at volume of 1 % is sprayed while mixing process is continued. After mixing process is continued for 2-5 minutes, homogenous mixture is transferred to the pellet section and it is converted to food containing veterinary drug.

Fish should be fasting for 12-24 hours before drug-food mixture is given to fish. The ratio of drug and feed may vary depending on temperature of water and size of fish.

SPECIAL CLINICAL INFORMATION AND SPECIAL WARNINGS FOR TARGET SPECIES

FLORVİL AQUA is a product used for manufacturing food containing drug. It is not directly administered.

ADVERSE EFFECTS

As long as it is administered orally at recommended doses, it has no side effects.

DRUG INTERACTIONS

It interacts with phenytoin, dicoumarol, talbutamide, phenobarbital and pentobarbital. Do not mix with the other products.

WITHDRAWAL PERIODS

Withdrawal period in fish varies depending on the water temperature. Fish should be harvested or not offered for consumption in accordance with this period. As the water temperature increases, the elimination of the drug from the body accelerates. During the treatment period and after the last drug application, fish should not be offered for human consumption until the total daily water temperatures reach 500°C.

CONTRAINDICATIONS
It should not be administered to studs. Florfenicols may prolong anesthesia period.

GENERAL WARNINGS
Consult a veterinarian before use and if any unexpected effects occur. Keep out of reach of children and fooding stuff.

PRECAUTIONS TO BE TAKEN BY THE ADMINISTRATOR AND WARNINGS FOR VETERINARY SURGEON
Avoid contact with the medication and wash your hands after use.
Necessary precautions should be taken to avoid contact with the medication during use.

STORAGE CONDITIONS AND SHELF LIFE
It should be stored in the original packages, protected from light, and stored below 25°C without placed in the refrigerator or freezer. Shelf life is 2 years.

COMMERCIAL PRESENTATION FORM
1 kg white polyethylene jars without boxes.

PLACE AND CONDITIONS OF SALE
It is sold in pharmacies, veterinary surgeries, polyclinics and animal hospitals with a veterinarian's prescription. (VSP)

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MARKETING AUTHORIZATION DATE AND NO: 24.08.2009-021/0078

MARKETING AUTHORIZATION HOLDER
VİLSAN Veteriner İlaçları Tic. ve San. A.Ş.
Balıkhisar Mah. Balıkhisar Köy İçi Küme Evleri No:765A Akyurt/Ankara-Türkiye

MANUFACTURER COMPANY
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Made in Turkiye