Leaflet and Label

For Veterinary Use Only

FAVETRİM AQUA

Oral Powder / Veterinary Medicated Premix

Veterinary Systemic Antibacterial

COMPOSITION

FAVETRİM AQUA Oral Powder / Veterinary Medicated Premix is a light yellow powder containing 416,7 g sulfadiazine and 83,3 g trimethoprim per kg.

PHARMACOLOGICAL PROPERTIES

FAVERİM AQUA Oral Powder / Veterinary Medicated Premix is a broad-spectrum formulation effective against many Gram-positive and Gram-negative bacteria (including penicillin-resistant ones) due to the synergistic effect of the combination of sulfadiazine and trimethoprim. This synergistic effect broadens the antibacterial spectrum and prevents the development of resistance. Sulfadiazine, a sulfonamide, inhibits the enzyme dihydrofolate synthase, which plays a role in dihydrofolic acid synthesis in susceptible bacteria. (Diaminoprimidine) derivative trimethoprim irreversibly inhibits the dihydrofolate reductase enzyme responsible for tetrahydrofolic acid synthesis, thereby blocking folic acid synthesis. As a result, the synthesis of bacterial nucleotides is disrupted, causing the bacterium's life functions to cease; reproduction stops, and the bacterium dies. While the active ingredients typically exhibit bacteriostatic effects when used alone, they exhibit bactericidal effects when used in combination.

Combination-sensitive bacteria: Gram-positive aerobes (*Bacillus* spp., *Corynebacterium* spp., *Erysipelothrix rhusopathiae, Listeria monocytogenes*, and *Streptococcus* spp.), Gram-negative bacteria (*Aeromonas* spp., *Flexibacter* spp., *Vibrio anguillorum, Vibrio salmonicida, Yersinia ruckerii, Pseudomonas* spp., *Haemophilus piscium, Cytophaga psycrophila, Bordetella* spp., *Francisella tularensis, Haemophilus* spp., *Pasteurella* spp., *Yersinia* spp., *Borrelia* spp., and *Leptospira* spp.), anaerobes (*Actinomyces* spp., *Fusobacterium* spp.), and *Mycoplasma* spp., *Chlamydia* spp., *Ehrlichia* spp., *Coxiella burnetti,* and Anaplasma are highly susceptible. Some *Mycobacterium* spp. and some *Nocardia* spp. are moderately susceptible. *Ricketsia* spp., *Leptospira* spp., *Pseudomonas aeruginosa* and *Mycoplasma* spp. are considered resistant.

When sulfadiazine was administered to carp at a dose of 100 mg/kg at 10°C, the $t_{½}$ was determined to be 47 hours, the V_d value was 0.53 L/kg, and the C_l value was 7.9.

AREA OF USE / INDICATIONS

It is effective against many gram-positive and gram-negative bacteria that cause diseases in freshwater and saltwater fish (sea bream, sea bass, trout). In cultured fish, it is effective against bacterial hemorrhagic septicemia (*Aeromonas hydrophila, Pseudomonas* spp.), columnaris disease (*Flexibacter columnaris*), red mouth disease (*Yersinia ruckerii*), streptococcal infections (hemolytic and non-hemolytic *Streptococcus* spp.), cold water vibriosis (*Vibrio salmonicida*), cold water disease, winter disease (*Pseudomonas anguiliseptica*), ulcer disease (*Haemeophylus piscium*), and juvenile rainbow trout syndrome caused by *Cytophaga psycrophila*.

USAGE AND DOSAGE

It is administered orally by mixing with feed.

Pharmacological dose: It is administered orally by mixing into fish feed at a rate of 60 mg sulfadiazine/kg body weight/day for 7-10 days.

Practical dose: It is administered orally by mixing into fish feed at a dose of 0.1 g powder/kg body weight/day for 7-10 days.

Rate of Fish Feed (According to Body Weight) (%)	**Rate of Favetrim Aqua, to be added to 1 Ton of Feed (kg)**	**Trimethoprim amount, which should be in 1 ton of feed (g)**	**Sulfadiazine amount, which should be in 1 ton of feed (g)**
0.5	12	1000	5000
1	6	500	2500
2	3	250	1250

Preparation of Feed with Drug:

The pre-measured FAVETRİM AQUA is placed in a clean, dry, and sensitive mixer or feed mixer. While mixing, 1% oil is sprayed. After it is mixed for 2–5 more minutes, the feed-medicine mixture becomes homogeneous and is ready for use. Before administering the medicated feed, the fish should be fasted for 12–24 hours. The medicated feed ratio may vary depending on the water temperature and the size of the fish.

SPECIAL CLINICAL INFORMATION AND SPECIAL WARNINGS FOR TARGET SPECIES

Yersinia ruckeri, which causes acute and chronic septicemia in salmonids, is a Gram (-) flagellated enteric bacillus that is transmitted by carrier fish through feces and should be taken into consideration in treatment and prevention. FAVETRİM AQUA is a veterinary medicated premix prepared for use in medicated feed and cannot be used directly on its own.

ADVERSE EFFECTS

It may cause allergic reactions for the animals susceptible to sulfonamides.

DRUG INTERACTIONS

Sulfonamides should not be used in combination with local anesthetics such as procaine, benzocaine, and butacaine, which are structural analogues of para-aminobenzoic acid (PABA) and contain a PABA core in their structure, as they may produce an antagonistic effect with procaine Penicillin G. B-complex vitamins such as nicotinamide, folic acid, and choline, as well as amino acids like glutamic acid and methionine, which are precursors to these vitamins, may also form antagonistic effects with sulfonamides.

WITHDRAWAL PERIODS

Withdrawal period for fish meat is 550 ^{o}C/day.

CONTRAINDICATIONS
It should not be used in animals with serious hepatic or renal disorders.

GENERAL WARNINGS
Consult a veterinarian before use and if any unexpected effects occur. Keep out of reach of children and fooding stuff. As the water temperature increases, the drug is excreted from the body more quickly.

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
Sold in pharmacies and veterinary clinics with a veterinary prescription. (VPR)

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NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER
VİLSAN Veteriner İlaçları Tic. ve San. A.Ş.
Balıkhisar Mah. Balıkhisar Köy içi Küme Evleri No:765A Akyurt/Ankara/Türkiye

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