

Leaflet

For Veterinary Use Only
FAVETRIM
Solution For Injection
Veterinary Systemic Antibacterial

COMPOSITION

Favetrim Solution for Injection; is a clear yellow solution containing 200 mg Sulfamethoxazole and 40 mg Trimethoprim per ml.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic Properties

Sulfamethoxazole is a member of the sulfonamide group of antibiotics and exerts its effect by substituting PABA, which is essential for DNA production during bacterial reproduction, in place of folic acid. It is effective against Gram-positive bacteria and certain protozoa, such as coccidia. Trimethoprim is a member of the diaminopyrimidine group and works by inhibiting the enzyme dihydrofolate reductase, which converts dihydrofolic acid to tetrahydrofolic acid. It is effective against streptococci and most Gram-negative bacteria. Both antibiotics act synergistically, and when used together, they provide a higher effect compared to a single application. Trimethoprim enhances the effect of sulfamethoxazole, resulting in a bactericidal effect against both Gram-negative and Gram-positive bacteria.

Pharmacokinetics Properties

Both substances are rapidly and well absorbed after administration. Peak plasma levels are reached 1-2 hours after administration. Both substances bind to plasma proteins at approximately 50%. Trimethoprim is more lipophilic and, therefore, has a higher volume of distribution. Trimethoprim is mainly excreted through urine and feces as a result of partial metabolism. Sulfamethoxazole, on the other hand, is primarily excreted through urine.

AREA OF USE/INDICATIONS

It is used for the treatment of respiratory, digestive, urinary, and soft tissue infections caused by bacteria sensitive to the combination in cattle, horses, cats, and dogs.

USAGE AND DOSAGE

In horses, it should be administered slow and intravenously and close to body temperature, while in other target species, it should be administered intramuscularly or slow intravenously. The recommended pharmacological dose is 16-24 mg of total active substance per kg body weight per day for cattle and horses, with a practical dose of 1 ml/10-15 kg body weight, daily. In cats and dogs, the pharmacological dose is 30 mg of total active substance per kg body weight, and practically, it is administered at a dose of 0.5 ml/4 kg body weight, daily.

For accurate dosage, the animals' body weight should be measured as precisely as possible. Intravenous administrations should be done slowly. The treatment duration is 3-5 days. If no

significant improvement is seen within 3 days after the first dose, the diagnosis should be reconsidered.

SPECIAL CLINICAL INFORMATION AND SPECIAL WARNINGS FOR TARGET SPECIES

To prevent kidney damage caused by crystalluria, adequate hydration should be maintained in the animals during treatment, and if necessary, urine should be alkalinized.

In horses, fatal anaphylactic or anaphylactoid reactions may occur after intravenous administration. Therefore, its use in horses should only be considered in life-threatening situations. After a small amount of the product is administered, the remaining product should only be used if no side effects are observed. If side effects appear during the first administration, the treatment should be stopped, and shock therapy should be applied if necessary.

The product should be warmed to body temperature before administration.

In individual cases, circulatory disturbances leading to death after intravenous administration in horses under anesthesia or sedation have been reported.

Use in newborns should be strongly justified.

This product should be used according to bacterial susceptibility tests and official and regional antimicrobial usage policies.

Using this product in a manner inconsistent with the usage instructions may lead to an increase in the prevalence of bacteria resistant to the combination and a decrease in the effectiveness of other sulfonamide/trimethoprim combinations due to cross-resistance, thereby reducing the overall effectiveness of the treatment.

Use during pregnancy: Studies in laboratory animals have shown teratogenic and fetotoxic effects at doses higher than the recommended doses, so it should not be used in pregnant animals.

ADVERSE EFFECTS

After administration, side effects ranging from irritation to necrosis may be observed at the injection site. Allergic reactions, changes in blood counts, liver and kidney damage may occur. It should be remembered that trimethoprim/sulfonamide combinations can have harmful effects on the liver, kidneys, and hematopoietic system in general.

In cattle, dyspnea and excitation have been observed in individual cases after intravenous administration.

In dogs, non-septic arthritis and keratoconjunctivitis sicca may develop.

Especially during long-term treatments with sulfonamides, symptoms such as hematuria, crystalluria, renal colic, and difficult urination due to crystal precipitation may rarely occur. If this condition is detected, the medication should be discontinued, and fluid therapy (with sodium bicarbonate supplementation) should be administered.

If allergic reactions develop, the medication should be stopped, and symptomatic treatment should be applied: Epinephrine and glucocorticoids intravenously for anaphylactic shock, and antihistamines and/or glucocorticoids for allergic skin reactions.

DRUG INTERACTIONS

It may have an antagonistic effect when combined with local anesthetics such as procaine penicillin G, benzocaine, procaine, and butacaine, which contain para-aminobenzoic acid in their structure. Vitamins from the B complex group, such as folic acid, nicotinamide, and choline, as well as their precursors like glutamic acid, methionine, valine, arginine, isoleucine, lysine, and some amino acids, also antagonize the effects of sulfonamides. When used together or following the use of diuretics (such as thiazides and furosemide), they may cause a significant decrease in platelet count. Enzymes, glucose, and compounds like mercuric chloride also have an antagonistic effect against sulfonamides. Indomethacin, phenylbutazone, and salicylates increase the blood levels of sulfamethoxazole.

Should not be mixed with other medicinal products.

SYMPTOMS OF OVERDOSE, PRECAUTIONS AND ANTIDOTE

Overdose of sulfonamides can cause ataxia, muscle twitching and cramping, coma, and liver damage. Nervous symptoms can be alleviated with centrally acting sedatives, such as barbiturates.

Vitamin K or folic acid administration, as well as alkalinizing agents like sodium bicarbonate, can be used in case of overdose.

If the urine pH is low due to disease or naturally low in carnivores, or if renal flow is reduced, crystallization of sulfonamides in the kidney tubules is expected, leading to hematuria, crystalluria, renal colic, and painful urination. If these symptoms persist, the medication should be discontinued, and appropriate fluid therapy should be administered (with sodium bicarbonate supplementation if necessary).

WITHDRAWAL PERIODS

Meat: 14 days for cattle

Milk: 5 days (10 milkings)

CONTRAINDICATIONS

Do not use in cases of aciduria.

Do not use in animals known to be sensitive to its components.

Do not use in the presence of bacteria resistant to the combination.

Do not use in animals with severe kidney and liver dysfunction.

Do not use in animals with hematopoietic system issues.

It should not be administered intravenously simultaneously with or after anesthetic, neuroleptic, or similar drugs that affect the central nervous system.

It should not be used in the presence of diseases that cause water loss or prevent adequate water intake.

Do not use in animals with cardiac arrhythmias.

Do not use in combination with bactericidal antibiotics.

GENERAL WARNINGS

Consult a veterinarian before use and if any unexpected effects occur. Keep out of reach of children and away from foodstuffs. Do not purchase or use products with expired shelf life or damaged packaging.

PRECAUTIONS TO BE TAKEN BY THE ADMINISTRATOR AND WARNINGS FOR VETERINARY SURGEON

People who are sensitive to sulfonamides or trimethoprim should avoid contact with the product. Do not use cigarettes or similar products, and do not eat or drink during application.

In case of eye or skin contact, rinse the area thoroughly with water. If symptoms such as redness occur after contact, consult a doctor with the product's usage instructions and label.

Swelling on the face, eyes, or lips, difficulty breathing, and similar symptoms are very serious and require immediate medical assistance.

STORAGE CONDITIONS AND SHELF LIFE

Before and after opening it should be stored in the original packages, protected from light, and stored below 25°C without placed in the refrigerator or freezer. The shelf life is 2 years.

DISPOSAL AFTER USE AND WARNINGS FOR NON-TARGET SPECIES

Used product packaging, unused or remaining product should be disposed of according to the relevant regulations.

COMMERCIAL PRESENTATION FORM

50 ml and 100 ml amber-colored Type II glass vials, with stoppers and flip-off caps with in a box.

PLACE AND CONDITIONS OF SALE

It is sold in pharmacies and veterinary clinics with a veterinarian's prescription. (VHP)

APPROVAL DATE OF LEAFET: 11.02.2025**MARKETING AUTHORIZATION DATE AND NO: 20.06.2006 – 016/0028****NAME AND ADDRESS OF 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

VİLSAN Veteriner İlaçları Tic. ve San. A.Ş.

Balıkhisar Mah. Balıkhisar Köy İçi Küme Evleri No:765A Akyurt/Ankara–Türkiye

Box

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WITHDRAWAL PERIODS

Meat: 14 days, Milk: 5 days (10 milkings).

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Made in Türkiye

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Label

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Withdrawal period (WDP): Meat: 14 days, Milk: 5 days (10 milkings).

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