Leaflet

For Veterinary Use Only

VİL-FLOKS

Solution for Injection

Veterinary Systemic Antibacterial

COMPOSITION

It is a clear pale yellow solution containing 100 mg enrofloxacin per ml.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Mechanism of Action

Two essential enzymes involved in DNA replication and transcription have been identified as molecular targets of fluoroquinolones: DNA gyrase and topoisomerase. Inhibition occurs by non-covalent binding of fluoroquinolones to these enzymes. Replication forks and translation complexes cannot progress beyond the enzyme-DNA-fluoroquinolone complex, leading to inhibition of DNA and mRNA synthesis, which triggers concentration-dependent rapid killing of pathogenic bacteria. Enrofloxacin exhibits a bactericidal effect that is dose-dependent.

Antibacterial Spectrum

At therapeutic doses, enrofloxacin is effective against most Gram-negative bacteria such as *Escherichia coli, Klebsiella* spp., *Actinobacillus pleuropneumoniae, Mannheimia haemolytica, Pasteurella* spp. (e.g., *Pasteurella multocida*), Gram-positive bacteria such as *Staphylococcus* spp. (e.g., *Staphylococcus aureus*), and *Mycoplasma* spp.

Resistance Mechanisms and Types

Five mechanisms of resistance development to fluoroquinolones have been reported:

- Point mutations in genes encoding DNA gyrase and/or topoisomerase IV enzymes, causing alterations in these enzymes,
- Altered permeability in Gram-negative bacteria,
- Efflux mechanisms,
- Gyrase protective proteins,
- Plasmid-mediated resistance.

All these mechanisms reduce bacterial susceptibility to fluoroquinolones. Cross-resistance among fluoroquinolones is common.

Pharmacokinetic Properties

Enrofloxacin is rapidly absorbed following parenteral administration, with high bioavailability (approximately 100% in calves). It binds to plasma proteins at a rate of about 20-50%. Enrofloxacin is metabolized into its active metabolite ciprofloxacin at about 40% in dogs and ruminants, and less than 10% in cats. It distributes into target tissues such as lungs, kidneys, and liver at concentrations 2-3 times higher than plasma levels. It also penetrates cerebrospinal fluid, crosses to the fetus in pregnant animals, and enters the aqueous humor of the eye. Both the parent compound and active metabolite are eliminated via the kidneys and feces.

AREA OF USE/INDICATIONS

Cattle

Effective against enrofloxacin-sensitive:
Respiratory system infections caused by *Pasteurella multocida, Mannheimia haemolytica*, and *Mycoplasma* spp. strains,
Acute severe mastitis caused by *Escherichia coli* strains,
Digestive system infections caused by *Escherichia coli* strains,
Septicemia caused by *Escherichia coli* strains,
Mycoplasma-associated acute arthritis caused by *Mycoplasma bovis* strains in cattle under 2 years of age.

Sheep

Effective against enrofloxacin-sensitive:
Digestive system infections caused by *Escherichia coli* strains,
Septicemia caused by *Escherichia coli* strains,
Mastitis caused by *Staphylococcus aureus* and *Escherichia coli*.

Goats

Effective against enrofloxacin-sensitive:
Respiratory system infections caused by *Pasteurella multocida* and *Mannheimia haemolytica* strains,
Digestive system infections caused by *Escherichia coli* strains,
Septicemia caused by *Escherichia coli* strains,
Mastitis caused by *Staphylococcus aureus* and *Escherichia coli*.

USAGE AND DOSAGE

Administer repeated injections at different sites.
Body weight should be calculated as accurately as possible to avoid underdosing.

Cattle

5 mg/kg body weight / day (1 ml/20 kg body weight) is administered once daily for 3-5 days. For acute arthritis caused by *Mycoplasma* in cattle younger than 2 years of age for 5 days.
Administer slow intravenous (IV) or subcutaneous (SC) injection.
5 mg/kg body weight per day (1 ml/20 kg body weight) is administered slow intravenously once daily for acute mastitis caused by *Escherichia coli*, for 2 days. The second dose can be given subcutaneously; in this case, the withdrawal period is determined according to the subcutaneous administration.
Do not administer more than 10 ml in one injection site.

Sheep and Goats

5 mg/kg body weight per day (1 ml/20 kg body weight) is administered once daily for 3 days subcutaneously.
Do not administer more than 6 ml in one injection site.

SPECIAL CLINICAL INFORMATION AND SPECIAL WARNINGS FOR TARGET SPECIES

Do not used for prophylactic purposes.
Do not exceed the recommended dose.
Repeated injections is administered at different sites.
Oral administration of enrofloxacin at a dose of 30 mg/kg body weight for 14 days in calves caused degenerative changes in articular cartilage.
Administration at the recommended dose for 15 days in growing lambs causes histological changes in articular cartilage without clinical signs.
Regional and national antimicrobial policies should be considered during use.
Improper use of this product, not according to the instructions in the summary of product characteristics, may lead to the development of bacteria resistant to fluoroquinolones and, due to possible cross-resistance, reduce the effectiveness of other quinolones.
Fluoroquinolones should be reserved for the treatment of clinical conditions that respond poorly or are expected to respond poorly to other antibiotics.
Use this product based on sensitivity test results of bacteria obtained from the animals.
If allergic reactions occur, treatment should be discontinued.
Since enrofloxacin is partially excreted via the kidneys, impaired renal function may slow its elimination and should be taken into account.
Intravenous use of this product in calves has not been proven safe and therefore should not be used intravenously.

Use during pregnancy:

Cattle: This product can be used during the first trimester of pregnancy. However, use in the last three trimesters depends on a benefit/risk assessment by the veterinarian. There is no objection to use during lactation.

Sheep and Goats: The safety of this product during pregnancy and lactation has not been established. Therefore, it should be used only based on a veterinarian's benefit/risk assessment.

ADVERSE EFFECTS

Local tissue reactions at the injection site may rarely occur. Very rarely, digestive disorders (such as diarrhea) may be observed. These symptoms are usually mild and transient.
Very rarely, intravenous administration in cattle may result in shock reactions.
The frequency of adverse effects is reported as follows:
Very common (more than 1 in 10 animals)
Common (more than 1 but less than 10 in 100 animals)
Uncommon (more than 1 but less than 10 in 1,000 animals)
Rare (more than 1 but less than 10 in 10,000 animals)
Very rare (less than 1 in 10,000 animals)

DRUG INTERACTIONS

Concurrent administration of enrofloxacin with antibiotics such as tetracyclines, phenicols, and macrolidescan cause to antagonistic effects.

Enrofloxacin should not be administered with theophylline because it slows the excretion of theophylline.

It should not be mixed with other medicinal products.

SYMPTOMS OF OVERDOSE, PRECAUTIONS AND ANTIDOTE

Do not exceed the recommended dose.

There is no antidote for overdose; symptomatic treatment should be applied.

There are no studies on overdose in calves, sheep, and goats.

Accidental overdose may cause digestive disorders such as vomiting and diarrhea, as well as neurological disorders.

Overdose can lead to dysfunction in the central nervous system and kidneys.

WITHDRAWAL PERIODS

Meat: 5 days after intravenous administration, 12 days after subcutaneous administration for cattle, 4 days for sheep, 6 days for goat.

Milk: 3 days after intravenous administration, 4 days after subcutaneous administration for cattle, 3 days for sheep, 4 days for goat

CONTRAINDICATIONS

Not to be used for prophylactic (preventive) purposes.

Do not use in cases where resistance to other fluoroquinolones is suspected due to possible cross-resistance.

Should not be used in animals with hypersensitivity to any of the components of the product.

Use cautiously in animals with a history of epilepsy or seizures, as enrofloxacin may stimulate the central nervous system.

Should not be used in growing horses due to potential significant damage to joint cartilage.

GENERAL WARNINGS

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

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

This product is alkaline. In case of contact with skin or eyes, wash thoroughly with plenty of water.

Do not eat, drink, or smoke while using the product.

Persons sensitive to fluoroquinolones should avoid contact with the product.

In case of accidental self-injection, seek medical attention immediately and show the product

leaflet and label to your doctor.
Wash your hands after use.
Use impermeable gloves during contact and application of the product.

STORAGE CONDITIONS AND SHELF LIFE
It should be stored below 25 °C, without refrigeration or freezing, in the original packaging, protected from light.
Shelf life is 3 years.

DISPOSAL AFTER USE AND WARNINGS FOR NON-TARGET SPECIES
Unused or leftover product must be disposed of in accordance with applicable regulations.

COMMERCIAL PRESENTATION FORM
20 ml, 50 ml and 100 ml amber colored glass vials in cardboard boxes.

PLACE AND CONDITIONS OF SALE
Sold with a veterinarian's prescription in pharmacies, veterinarian offices, polyclinics and animal hospitals. (VHR)

APPROVAL DATE OF LEAFLET: 16.08.2023

MARKETING AUTHORIZATION DATE AND NO: 13.03.2001-10/931

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

MANUFACTURER COMPANY
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Made in Turkiye

Box

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GENERAL WARNINGS

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SERI NO:
MFG. DATE: **EXP. DATE:**

Label

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