Leaflet

For Veterinary Use Only

TAVILIN 200

Solution For Injection

Veterinary Systemic Antibacterial

COMPOSITION

It contains 200 mg of tylosin per ml.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Tylosin is a macrolide group antibiotic with a pKa of 7.1. Structurally, it is similar to erythromycin. It is produced by Streptomyces fradiae. It has low solubility in water. Similar to other macrolides, it exerts its effect by binding to the 50S ribosomal fraction in bacteria, thereby inhibiting protein synthesis. It is primarily bacteriostatic. Its spectrum of activity includes Gram-positive cocci (Staphylococci, Streptococci), Gram-positive bacilli (such as Erysipelothrix), some Gram-negative bacilli, and Mycoplasma.

Tylosin resistance is typically plasmid-mediated, but chromosomal mutations resulting in ribosomal modification can also occur. Resistance develops through reduced bacterial uptake (most commonly in Gram-negative bacteria), the synthesis of bacterial enzymes that hydrolyze tylosin, and modification of the target region (ribosome). The latter type of resistance may lead to cross-resistance with macrolides that bind bacterial ribosomes. Gram-negative bacteria are frequently resistant.

Pharmacokinetics Properties

Absorption: Following intramuscular administration, the tylosin concentration reaches its maximum level 3-4 hours after administration.

Distribution: Six hours after administration, the maximum concentration in bovine milk is 3-6 times higher compared to plasma. Six to 24 hours after intramuscular administration, the concentration in the bovine lung reaches 7-8 times the serum concentration.

In cattle, intravenous administration of a 10 mg/kg dose results in an average retention time in uterine secretions that is 6-7 times longer than in serum. This leads to concentrations above the MIC90 value required for Arcanobacterium pyogenes, which is commonly isolated in bovine metritis.

Elimination: Tylosin is excreted unchanged in bile and urine.

AREA OF USE/INDICATIONS

Cattle (adult):

Treatment of metritis caused by Gram-positive bacteria, respiratory system infections, mastitis caused by Streptococcus spp. and Staphylococcus spp., and interdigital necrobacillosis caused by Fusobacterium necrophorum.

Calves:

Necrobacillosis (Fusobacterium necrophorum) and respiratory system infections.

Sheep-Goats:

Treatment of metritis caused by Gram-positive bacteria, respiratory system infections, mastitis caused by Gram-positive bacteria or Mycoplasma spp..

Dogs:

Treatment of respiratory system infections and otitis caused by susceptible bacteria.

Cats:
Used for respiratory system infections caused by susceptible bacteria.

USAGE AND DOSAGE
Intramuscular and exclusively in cattle, slow intravenous administration.
Cattle: Administered at a dose of 5-10 mg/kg body weight/day for 3 days (2.5-5 ml per 100 kg body weight per day). A maximum of 15 ml should be administered to a single injection site.
Sheep-Goats: Administered at a dose of 10 mg/kg body weight/day for 3 days (2.5 ml per 50 kg body weight per day).
Cats-Dogs: Administered at a dose of 7-11 mg/kg body weight/day for 3-5 days (0.35-0.55 ml per 10 kg body weight per day). A suitable syringe capable of accurate dosing for small amounts should be used.
To prevent excessive puncturing of the vial, an appropriate multi-dose tool should be used. For accurate dosing, the animal's weight should be measured as precisely as possible.

SPECIAL CLINICAL INFORMATION AND SPECIAL WARNINGS FOR TARGET SPECIES
Due to differences in bacterial sensitivity to tylosin, it is recommended to perform microbiological sampling and sensitivity testing.
Using this product in a manner different from the instructions can lead to an increase in the prevalence of tylosin-resistant bacteria and, due to potential cross-resistance, a decrease in the effectiveness of other macrolides. Official, national, and regional antimicrobial policies should be considered when using the product.
Effectiveness data do not support the use of this product for bovine mastitis caused by Mycoplasma spp.
For repeated injections, administer to different sites.
Use during pregnancy, lactation period:
Studies in laboratory animals have not shown evidence of teratogenic, fetotoxic, or maternotoxic effects. There is no study on target species during pregnancy and lactation. It should only be used based on a veterinarian's benefit/risk assessment.

ADVERSE EFFECTS
After administration, discoloration at the injection site may be observed, which can last up to 21 days.
Very rarely in cattle, vulvar edema, swelling and inflammation at the injection site, anaphylactic shock, and edema have been reported.
The following conversion is used when reporting the frequency of undesirable effects:

- Very common (more than 1 in 10 animals)
- Common (more than 1 but fewer than 10 in 100 animals)
- Uncommon (more than 1 but fewer than 10 in 1,000 animals)
- Rare (more than 1 but fewer than 10 in 10,000 animals)
- Very rare (fewer than 1 in 10,000 animals)

DRUG INTERACTIONS
Lincosamides and aminoglycosides may antagonize the effect of tylosin. Do not mix with other products.

SYMPTOMS OF OVERDOSE, PRECAUTIONS AND ANTIDOTE
No side effects have been observed with a 30 mg/kg dose administered for 5 consecutive days in calves.

WITHDRAWAL PERIODS
Meat: 28 days for cattle, 42 days for goats and sheep
Milk: 108 hours (9 milkings).

CONTRAINDICATIONS
Do not administer to horses or other single-hoofed animals, as it may cause death. Intramuscular administration in chickens and turkeys may be fatal.
It should not be administered to animals known to be sensitive to the excipients and active ingredients in the composition or to other macrolide antibiotics.

GENERAL WARNINGS
Consult a veterinarian before use and if any unexpected effects are observed. Keep out of reach of children.

PRECAUTIONS TO BE TAKEN BY THE ADMINISTRATOR AND WARNINGS FOR VETERINARY SURGEON
Necessary precautions should be taken to avoid accidental self-injection.
In case of accidental self-injection, seek emergency medical treatment.
In case of skin contact, wash the area thoroughly with plenty of water and soap. In case of eye contact, rinse the eye with plenty of water under running water.
Wash hands after use.
Tylosin may cause irritation. Injection, inhalation, oral ingestion, or skin exposure to macrolides like tylosin may lead to hypersensitivity (allergic) reactions. Hypersensitivity to tylosin may cause cross-reactivity with other macrolides (or vice versa). Allergic reactions can rarely be severe, so direct contact should be avoided.
If you are sensitive to any of the components, do not use the product. If symptoms like redness on the skin occur, go to a doctor and show this warning to receive prompt treatment. Swelling of the face, lips, or eyes, or difficulty breathing are very serious symptoms and require immediate medical treatment.

STORAGE CONDITIONS AND SHELF LIFE
Before and after opening, the product should be stored below 25°C, in the original packages, without being frozen or placed in the refrigerator. Protect from sunlight. Shelf life is 2 years.

DISPOSAL AFTER USE AND WARNINGS FOR NON-TARGET SPECIES
Used or leftover product should be disposed of in accordance with relevant regulations.

COMMERCIAL PRESENTATION FORM
50 ml and 100 ml amber-colored glass vials with cardboard boxes.

PLACE AND CONDITIONS OF SALE
It is sold in pharmacies and veterinary clinics with a veterinarian's prescription. (VHP)

APPROVAL DATE OF LEAFLET:19.10.2022

MARKETING AUTHORIZATION DATE AND NO: 06.09.2001 – 10/967

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

MANUFACTURER COMPANY
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Made in Turkiye

Box

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Read the leaflet for detailed information

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