

**For Veterinary Use Only**

# **Tiloseptin<sup>®</sup>**

**Oral Granule**

**Veterinary SYSTEMIC Antibacterial**

## **COMPOSITION**

Tiloseptin Oral Granule is a yellowish viscous granule, and every single Tiloseptin 100 g package contains tylosin tartrate equivalent to 100 g tylosin base.

## **PHARMACOLOGICAL PROPERTIES**

Tylosin is a macrolide antibiotic obtained from *Streptomyces fradiae* cultures. It bonds to 50 S subunit in bacterial ribosome, and then inhibits the translocation step. Tylosin is efficient against main gram positive bacteria. Primarily tylosin sensitive bacteria are:

*Mycoplasma* sp., *Leptospira* sp., *Erisipelas* sp., *Haemophilus pertusii*, *Moraxella bovis*, *Borrelia anserina*, *Treponema hyodysenteria*. Tylosin is very efficient in infections especially the ones generated by *Mycoplasma gallisepticum*. Resistant strains may be involved in staph. aureus strains.

It is rapidly and mostly absorbed orally and reaches the therapeutic blood concentration within 1 hours. Its concentration in respiratory tract reaches to a few fold plasma concentration. It becomes included also in milk and egg significantly. 90% of tylosin is excreted through intestines via ballast after all of tylosin being metabolized in liver essentially. Milk and egg are also one of the important excretion ways. Around 2-5% of it is excreted through urination.

## **AREA OF USE/INDICATIONS**

In Chicken and Hens

In meat type and breeding chicken, in treatment for chronic respiratory disease (CRD) caused by tylosin sensitive *Mycoplasma gallisepticum* and *Mycoplasma synoviae*,

In Turkeys

It is used in treatment for sinusitis infection caused by tylosin sensitive *Mycoplasma gallisepticum*.

## **USAGE AND DOSAGE**

Unless recommended otherwise by veterinary surgeon,

Pharmacologic dose;

For Chicken :100 mg tylosin/ kg live weight/day

For Turkeys :120 mg tylosin/ kg live weight/day

A 100 g package is the daily administration dose for a total of 1000 kg live weight in meat type hens, and for a total of 830 kg live weight in turkeys. Required powder is used after mixing it with the water they drink in a day. Drugged water should be prepared freshly everyday during the treatment. 2-3 hours before drugged water administration it is recommended animals to be let without water. Therapies should be maintained for 3-5 days as per the condition of illness.

## **UNDESIRE/SIDE EFFECTS**

No known side effects or toxic effects were observed when administering orally.

**DRUG INTERACTIONS**

Avoid using together with macrolide antibacterials, phenicols with similar action style, lincosamides, and other macrolides.

**SYMPTOMS OF OVERDOSE, PRECAUTIONS AND ANTIDOTE**

It has been observed that tylosin has a broad security limit in all animal species consequent to acute, subacute, and chronic toxicity studies.

**WARNINGS ON DRUG RESIDUES IN FOOD**

Withholding Period (WHP): Meat type chicken should not be sent for slaughtering before 2 days after the last drug administration, and turkeys before 5 days after the last drug administration.. The drug should not be used in layer chickens and turkeys whose eggs are offered for human consumption.

**GENERAL WARNINGS**

Consult your veterinary surgeon before using and in case an undesired effect is observed. Keep out of reach of children. Do not purchase and use the products with damaged packages.

**PRECAUTIONS TO BE TAKEN BY THE USER AND WARNINGS FOR VETERINARY SURGEONS**

It has been reported preparators may show rash-type mild skin reactions as a result of long-term contacting tylosin tartrate. A mask, protective gloves and clothing should be used during product usage. In case of skin contact, wash with plenty of water.

**STORAGE CONDITIONS AND SHELF LIFE**

The product should be stored at room temperature (15 – 25 °C) and should be protected from light, and should not be frozen. Shelf life is 2 years as of the production date.

**COMMERCIAL PRESENTATION FORM INDICATING THE QUALITY AND QUANTITY OF THE PACKAGE**

In white polyethylene jars of 100 g, 500 g, and 1000 g. 100 g packages are offered for market as parcels for 10 pieces, and with 10 package inserts bonded to package in each parcel.

**PLACE AND CONDITIONS OF SALE**

It is provided in pharmacies, veterinary private hospitals, and veterinary clinics, and subject to veterinary surgeon's prescription. VSP

**APPROVAL DATE OF PACKAGE INSERT:** 21.09.2004

**MINISTRY OF AGRICULTURE AND RURAL AFFAIRS MARKETING AUTHORIZATION DATE - NO:**  
22.03.2002-11/1024

**NAME AND ADDRESS OF MARKETING AUTHORIZATION OWNER:**

**Alke Sağlık Ürünleri San. ve Tic. A.Ş**

Dolayoba, Çınardere Mh. 3. Petek Sk. No: 18, 34896 Pendik-ISTANBUL

**NAME AND ADDRESS OF MANUFACTURER COMPANY:**

**Alke Sağlık Ürünleri San. ve Tic. A.Ş**

Merkez Organize Sanayi Bölgesi 2. Kısım 10. Cadde No:7 Tokat