

**For Veterinary Use Only.**

# Actimisin<sup>®</sup> AK

**Concentrate Oral Solution**

**Veterinary Systemic Antibacterial**

## COMPOSITION

A light yellow-amber coloured antibacterial solution containing 250ml tilmicosin in each ml.

## PHARMACOLOGIC PROPERTIES

It contains tilmicosin, a semi-synthetic macrolide group antibiotic. Due to its particularly high affinity for the lung tissue, tilmicosin is used for the treatment of pneumoniae infections.

Mechanism of actions, to prevent the bacterial protein synthesis through binding to 50S ribosomal subunits and inhibiting peptide formation as other macrolides. Gram positive bacteria species and some gram negative bacteria species such as, *Pasteurella haemolytica*, *Haemophilus sumnus*, *Pasteurella multocida*, *Mycoplasma gallisepticum*, *M. synovia*, *Mycoplasma dispar*, *Ornithobacterium* are sensitive to tilmicosin. *E.coli*, *Enterobacter aerogenes*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Salmonella* and *Serratia sp.* and *Actinomyces sp.* are resistant. Tilmicosin has low serum concentration but high tissue distribution characteristic like the other macrolid antibiotics. It is measured that the max. plasma level is 10 µg/ml after 84 hours from the administration when the tilmicosin is administrated orally 75mg/L for three days for broiler chickens. It is reported that lung tissue level is 2.3 µg/ml and air sac tissue concentration is 3.29 µg/ml after 48 hours from administration. Tilmicosin is excreted mainly by bile.

## FIELD OF APPLICATION/INDICATIONS

It is used for treatments of respiratory tract infections on turkeys and broiler caused by *Mycoplasma gallisepticum*, *M. synovia*, *Ornithobacterium rhinotracheale*, *Pasteurella multocida* and other microorganism sensitive to tilmicosin.

## ADMINISTRATION AND DOSE

Dosage of tilmicosin for turkeys and broiler is 15-20 mg/kg live body weight per day. 60-80 ml medicine is added into the drinking water for three days for 1000kg live body weight as a daily dosage. Unless recommended otherwise by the Veterinary Surgeon, the dosage is practically calculated as it is given below. The Actimisin AK Concentrate Oral Solution dosage for one day is:

$$\text{Actimisin AK Concentrate Oral Solution (ml)} = \frac{\text{Number of animals} \times \text{Average Live Body Weight (kg)} \times 15}{250}$$

Average Live Body Weight (kg)	Daily dosage of Actimisin AK Concentrate Oral Solution for 1000 animals (ml)
0.25	15
0.50	30
0.75	45
1.0	60
1.25	75
1.50	90
1.75	105
2.0	120

### **UNDESIRABLE/ADVERSE EFFECTS**

Tilmicosin may cause increase in heart beat rate and decrease in contraction power.

### **DRUG INTERACTIONS**

Usage with chloramfenicol, florfenicol, lincosamides and other macrolid antibiotics will cause competitive antagonism. Beta adrenergic antagonists (e.g. propranolol) may increase the tilmicosin based tachycardia..

### **OVERDOSE SIGNS, PRECAUTIONS AND ANTIDOTE**

In the case overdose, risk of cardiac toxicity will increase. No specific antidote is known. The beta adrenergic antagonists as Propranolol are not recommended because of decreasing the contraction power of heart in spite of decreasing the tachycardia.

### **WARNINGS FOR THE DRUG RESIDUES IN FOOD**

Withholding Period (WHP): Chickens and turkeys being grown for human consumption should not be slaughtered before 14 and 10 days, respectively, following the drug administration. The drug should not be used for chickens and turkeys produce egg for human consumption.

### **CONTRAINDICATIONS**

Macrolide antibiotics are metabolized in liver, therefore it should not be used in animals with hepatic disorders..

### **GENERAL WARNINGS**

Veterinary surgeon should be consulted before the administration and in the case of adverse effects. Keep away from children. Use only in target species.

### **SPECIAL PROTECTION MEASURES FOR THE ADMINISTRATOR AND WARNINGS FOR THE SURGEONS**

If sensitive people expose to it by orally, skin or inhalation it may cause swelling on face and lips and difficulty in respiration. If these signs occurs, urgent medical attention will be needed. A doctor should be consulted with the prospectus in the case of accidental poisoning. Wash your hands after usage. Tilmicosin can be fatal on human.

### **STORAGE CONDITIONS AND SHELF LIFE**

Store at room temperature of not more than 25 °C (15-25 °C). Keep away from direct sunlight. A shelf life of 2 years(24 months) has been reported from the date of manufacture.

### **DISPOSAL AFTER APPLICATION AND WARNINGS FOR NON-TARGET SPECIES**

The drug should be disposed together with its package (bottle) in case it is expired, opened or kept for a long period without observing the storage conditions. Tilmicosin can fatal on cats, dogs, monkeys and goats.

### **COMMERCIAL PRESENTATION FORM**

The solution is presented in 60 ml, 240 ml 480 ml and 960 ml amber colored glass and PET bottles in carton boxes.

### **SELLING AREA AND CONDITIONS**

To be sold in pharmacies and veterinary clinics upon prescription of veterinary surgeon (Veterinary Surgeon Prescription)

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

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