

Only For Use in Animal Health

# Necrolin-N<sup>®</sup>

Oral Solution

Veterinary Antibacterial

## COMPOSITION

Necrolin Oral Solution is a clear, yellowish antibacterial solution containing HCL salt equivalent to 250 mg lincomycin base and neomycin sulphate equivalent to 140mg neomycin base in each ml.

## PHARMACOLOGIC PROPERTIES

It is an oral antibacterial solution containing lincomycin, a lincosamide antibiotic and neomycin, an aminoglycoside antibiotic. As the actions of lincomycin and neomycin are based on inhibition of protein synthesis develop consecutively and sequentially, their bactericidal effects are irreversible. Staphylococcus species, B haemolytic streptococcus, Clostridium perfringens, Mycoplasma sp, Neisseria sp, Actinomyces sp, Corynebacterium sp and Campylobacter sp are susceptible and all aerobic Gram negative bacillus, Nocardia and Mycobacterium species are resistant to lincomycin. As Gram negative bacteria E.coli, Enterobacter aerogenes, Pasteurella sp, Pr. vulgaris, Salmonella sp, Shigella sp, H.influenza; as Gram positive bacteria B. Anthracis, Borrelia sp, Staph.aureus, Str.faecalis, L.monocytogenes are susceptible and anaerobic bacteria, Streptococcus pyogenes and streptococcus viridans is resistant to neomycin. Lincomycin inhibits the peptide chain formation by conjugating the 50S ribosomal subunit on the susceptible bacteria. It will be absorbed very fast as it is administered orally and will reach the peak blood concentration within 1-2 hours. It penetrates in serum and tissues mostly. Tissue concentrations are higher than serum concentration. It will be excreted by stools and urine. Bioavailability changes between 40%-60% depending on fullness of the stomach. Effect mechanism of neomycin bases on inhibiting the protein synthesis of bacteria by preventing mRNA conjugation to 30S ribosomal subunits and inducing misread of the codons on RNA. It is used in treatment of bacteria existing in alimentary canal in pets as a result of low absorption rate (3%) when it is administered orally. Neomycin is a resistant antibiotic to acidic environments. It keeps its antibacterial function as it does not part in intestine for a long time when it is administered orally. As a result of its polarity and cationic structure, absorption of neomycin sulphate is very low when it is administered orally. It does not reach the therapeutic dose. Hence, it is not convenient for oral administration treatment of systemic infections. 97% of the drug is excreted by stools in active form as the main composition. A very low rate absorbed neomycin penetrates the body very fast, conjugates to proteins at a very low rate and excreted by urine.

## FIELD OF APPLICATION/INDICATIONS

It is used for treatment of common respiratory infections caused by the susceptible bacteria in chickens, staphylococcus infections, streptococcus infections, necrotic enteritis and treatment of enteritis caused by susceptible bacteria such as E.coli, Salmonella, Haemophilus, Pseudomonas, Proteus.

## ADMINISTRATION AND DOSE

It is used orally for chicken by adding it into their drinking water. Unless recommended otherwise by the Veterinary Surgeon, neomycin is used as 10mg/kg live body weight per day and lincomycin is used as 20-25mg/kg live body weight per day. Practically, 100ml oral solution is added into the drinking water for 1000kg live body weight and the treatment proceeds 3-5 days. For poultry farm treatment dose calculated as daily should be added into the drinking water freshly every day.

### **UNDESIRABLE/ADVERSE EFFECTS**

It is observed that pigs, ruminants and laboratory animals suffered from chronic diarrhea and anus oedema after oral administration. Adverse or toxic effect is not known for poultry animal.

### **DRUG INTERACTIONS**

Lincomycin is incompatible with erythromycin pharmacologically. Absorbents (kaolin) used for antidiarrhetic purposes may decrease the absorption ratio. Simultaneous usage should be avoided as drug antagonism may occur between lincomycin and erythromycin and fenicol. Antibacterial effect of neomycin will decrease in acidic environments and environments comprising divalent mineral in high concentrations. In spite of low absorption when it is administered orally, it should not be used with aminoglycosides, ototoxic effecting neuromuscular blockage, neurotoxic, and drugs known as nephrotoxic, other aminoglycosides and furosemides, cephalosporin, methoxyflurane, amphotericin B, polymyxin and tetracycline.

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

Lincomycin and neomycin are safe drugs when they are administered orally. For lincomycin doses over 8000mg/kg may cause depression, diarrhea and convulsion. For neomycin it is over LD50 2000mg/kg. A specific antidote is not known.

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

Withholding Period (WHP): The chicken should not be slaughtered during the treatment and before 2 days following the last dose. Eggs produced by treated chickens should be consumed by human during the treatment and before 2 days following the last dose.

### **CONTRAINDICATIONS**

There is no contraindication known for poultry animals.

### **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**

It should not contact with eyes. Direct contact with the skin should be avoided by using gloves.

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

Store it in its original package at room temperature of not more than 25 °C (15-25 °C). Keep away from direct sunlight.

### **COMMERCIAL PRESENTATION FORM**

It is presented in 100, 500, 1000, 2500ml and 5L white plastic bottles.

### **SELLING AREA AND CONDITIONS**

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

**DATE OF APPROVAL OF THE PACKAGE INSERT: 13.02.2006**

**DATE AND NUMBER OF THE AUTHORIZATION OF THE MINISTRY OF AGRICULTURE AND RURAL AFFAIRS: 15.12.2005-15 /049**

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

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

Dolayoba, Çınardere Mh. 3. Petek Sk.

No: 18, 34896 Pendik-ISTANBUL

**NAME AND ADDRESS OF MANUFACTURER COMPANY:**

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

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