

For Veterinary Use Only

Enrolen[®]

10% Oral Solution

Veterinary Oral Antibacterial

COMPOSITION

Enrolen Oral Solution is a clear, yellowish, odourless, viscous solution containing 100mg enrofloxacin per each ml.

PHARMACOLOGICAL PROPERTIES

Enrofloxacin is an antibiotic which belongs to the fluoroquinolones group and it is widely used in veterinary field with its broad effect spectrum. It is safely used for the treatment and prevention of infections caused by Gram (+) and Gram (-) bacteria and mycoplasmas. Enrofloxacin is an antibiotic which is rapidly and readily absorbed orally demonstrating a good diffusion profile in the organism. It reaches the maximum plasma level within an hour following its administration. Its concentrations in the tissues reach a few times of the level in serum and it maintains its effective level for 12-24 hours. Enrofloxacin is an antibacterial which inhibits topoisomerase (DNA gyrase) functioning in the bacterial DNA synthesis and acts as a bactericide at low concentrations. Enrolen Oral Solution is effective over bacteria which are resistant to other antibacterials due to its special mechanism of action.

AREA OF USE/INDICATIONS

It is used for the treatment and prevention of infections caused by Gram (+) and Gram (-) bacteria that are sensitive to enrofloxacin.

It is indicated in the treatment of bacterial or mycoplasmal infections in the respiratory and digestive system of poultry.

Effect Spectrum:

- E.coli
- Yersinia spp.
- Acinetobacter spp.
- Citrobacter spp.
- Salmonella spp.
- Serratia spp.
- Pasteurella spp.
- Shigella spp.
- Vibrio cholerae
- Chlamydia spp.
- Corynebacterium spp. resistant to penicillin
- Mycoplasma gallisepticum, Mycoplasma synoviae and mixed contaminations
- Providencia spp.
- Moraxella spp.
- Campylobacter spp.
- Haemophilus spp.
- Enterobacter spp.
- Proteus spp.

- Klebsiella spp.
- Staphylococcus spp. resistant to methicilline and gentamicine
- Group A,B,D Streptococcus

Pasteurellosis, Mycoplasmosis (CRD and CCRD Chronic and Complicated Chronic Respiratory Disease), Salmonellosis, Colibacillosis, Colisepticemia, Staphylococcosis cases.

USAGE AND DOSAGE

Enrolen 10% Oral Solution which has been formulated for poultry is administered orally by adding into drinking water as per the calculation of 10mg/kg/day general enrofloxacin dose. It is used for 3-10 days according to the reason and severity of infections and the anticipation of the Veterinary Surgeon. The daily required amount of Enrolen Oral Solution 10% for 1000kg live weight in poultry is 100ml.

SPECIFIC CLINICAL INFORMATION AND SPECIAL WARNINGS FOR TARGET SPECIES:

Fluoroquinolones are broad spectrum antibiotics including Gram (+), Gram (-) bacteria and mycoplasmas. However, they are not effective for anaerobic bacteria at treatment doses.

UNDESIRE/SIDE EFFECTS

Although certain side effects are observed in humans and carnivores such as the irritation of digestive system, dizziness, tremors, confusion and increment in candida infections, no similar effects are seen in poultry.

DRUG INTERACTIONS

Enrofloxacin has synergistic interactions with aminoglycosides, beta-lactam antibiotics and sulphonamides; whereas antagonist interactions with chloramphenicol, erythromycin, polymyxin, nitrofurantoin and rifampin.

SYMPTOMS OF OVERDOSE, PRECAUTIONS AND ANTIDOTE

Enrofloxacin is a toxicologically safe antibiotic. Broiler chickens of 1-21 days and turkeys of 1-6 weeks are tolerant of 250-300ppm enrofloxacin administered with water.

WARNINGS ON DRUG RESIDUES IN FOOD

Withholding Period (WHP); Broiler chickens and turkeys should not be sent for slaughter during the treatment and before 14 days and 12 days, respectively, after the final administration. It is not administered to turkeys and chickens whose eggs are used for human consumption.

CONTRAINDICATIONS

No contraindication specified in on poultry.

GENERAL WARNINGS

It is sold with Veterinary Surgeon prescription. Keep out of reach of children.

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

The medicated drinking water should be prepared and used daily. During the administration the applicator should avoid eating or drinking.

STORAGE CONDITIONS AND SHELF LIFE

Store in a dry and cool place. Protect from light. Shelf life is 2 years as of the production date.

WARNINGS FOR NON-TARGET SPECIES:

Fluoroquinolones may result in disorders of cartilage tissue development in dogs and horses during the phase of bone development. It may cause blindness, convulsion and depression in cats; whereas nervous reactions in dogs such as ataxia, collapse and depression.

COMMERCIAL PRESENTATION FORM INDICATING THE QUALITY AND QUANTITY OF THE PACKAGE

Offered for sale in 100, 500 and 1000ml high-density polypropylene, white coloured plastic packages. As for 100ml packages, the cardboard box is within the outer package.

PLACE AND CONDITIONS OF SALE

Sold with Veterinary Surgeon's prescription in pharmacies and veterinary surgeries.

APPROVAL DATE OF PACKAGE INSERT: 21.09.2004

MINISTRY OF AGRICULTURE AND RURAL AFFAIRS MARKETING AUTHORIZATION DATE - NO

23.09.1996 - 8/766

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