Only For Veterinary Use.

Enrolen® Forte

Oral Solution

Veterinary Systemic Antibacterial

COMPOSITION

Enrolen Oral Solution is a clear, odorless, yellowish fluid solution containing 200mg enrofloxacin per milliliter.

PHARMACOLOGICAL PROPERTIES

Enrofloxacin is a broad spectrum antibacterial, which is an antibiotic belonging to the group of floroquinolones. Enrofloxacin mechanism of action as inhibiting the topoisomerase (DNA girase) in the bacterial DNA systhesis and it has a bactericidal effect at low concentrations

The main susceptible bacteria are E.coli, Salmonella sp., Enterobacter sp., Serratia sp., Proteus sp., Klebsiella sp., Shigella sp., Yersinia sp., Moraxella sp., Acinobacter sp., Actinobacillus sp., Pasteurella sp., Leptospira sp., Campylobacter sp., Citrobacter sp., Haemophilus sp., Ehrlichia sp., Coxiella brunetti, Staphylococcus sp. including the ones resistant to methicilline and gentamycine, N.gonorrhoeae, N. meningiditis, Corynebacterium sp., Chlamydia sp., V.cholerae, Mycoplasma sp including the ones resistant to penicillin.

The susceptibility of Strep. suis, Strep. agalactia, Strep dysgalactia, Strep. zooepidemicus, R.equi, Mycobacterium sp is moderate.

Most of anaerobic bacteries, Clostridium sp., Bacteroides sp., and Ps. Maltophila are often either less susceptible or resistant to quinolones.

Enrofloxacin, which is rapidly and readily absorbed through oral route, is an antibiotic with an efficient dispersion profile in organism. It reaches a maximum plasma level within an hour following its administration. The concentrations of the drug in the tissues reach a level that is a few times more than the level in the serum and it maintains its efficiency for a period of 12-24 hours. When it is administered on chicken, time for reaching the maximum blood concentration is 1.43 hour and maximum blood concentration is 2.44 ± 0.64 µg/ml. When administered orally, its elimination half-life is 14.9 hours for chicken and 6.2 hours for turkeys. The distribution volume for chicken and turkeys is 3.61 l/kg and 3.16 I/kg, respectively. It is excreted through urine with a ratio of approximately 45%.

AREA OF APPLICATION/INDICATIONS

The drug is used in carnivorous, chicken and turkeys for the treatment of infections originated from bacteria that are susceptible to enrofloxacin. Within this scope it is indicated for septicaemia and diearrhea arising from E. coli; Colibacillosis; yolk sac infections; Salmonellosis, M. gallisepticum, M. synoviae, M. Meleagridis, M. Iowae infections; infections and mixed infections related to Pasteurellosis, Staphylococcosis, Pseudomonas aeroginosa, H. gallinarum, E. Rhusipathia factors, and the infections that arise from the secondary bacterial factors of the viral diseases.

ADMINISTRATION AND DOSE:

Enrolen Oral Solution 20%, 10mg/kg, which is formulated for carnivorous chicken and turkeys, is injected into drinking water by being calculated with the general enrofloxacin dose based on live body weight/day, and then administered orally. The medicated drinking water should be prepared and used on a daily basis. It is used for 3-10 days depending on the reason and intensity of the infections and the pre-cognition of the Veterinary Surgeon. The daily quantity required by the carnivorous chicken is 50ml of Enrolen Oral Solution 20% for a live body weight of 1000kg.

UNDESIRED/ADVERSE EFFECTS

Certain quinlones may sometimes cause crystallization in urinary tracts, such as ciprofloxacin and enrofloxacin. Therefore, water limitation should be avoided during the administration of these drugs.

DRUG INTERACTIONS

The interactions of floroquinolones with beta-lactame medicines and sulfonamides are synergistic; whereas erythromycin, polymyxin, nitrofurantine and rifampin have antagonist interactions. The drug should not be used together with bivalent and trivalent minerals such as aluminium, iron, magnesium, calcium since they develop chelation. It must be used at least 2-3 hours before or after the administration of the products consisting of these kinds of minerals. Due to the fact that enrofloxacin has a potential of developing chelat during oral administration with metals, particularly as Cu, Pb, Zn, Mg, Al; it is not recommended to be used in water which is rich in these metals. Since quinolones are affected by the ambient pH, they should be avoided to be used with materials that acidifies the drinking water. The administration of enrofloxacin together with the other medicines known to be metabolised in the liver, may have an effect on the pharmacokinetics of the respective drugs.

SIGNS, PRECAUTIONS AND ANTIDOTE FOR OVERDOSE

Enrofloxacin is a safe antibiotic in terms of toxicology. 250 – 300 ppm enrofloxacin admistered with water is tolerable by 1-21 days old chicks and 1-6 weeks old turkeys.

WARNINGS FOR THE DRUG RESIDUES IN FOOD

Withholding Period (WHP): The chicken and turkeys that are being grown for human consumption should not be slaughtered during the treatment or before 12 and 14 days, respectively, following the drug administration. Not recommended to be administered to the chicken from which eggs for human consumption are produced.

CONTRAINDICATIONS

There are no contraindications available determined for the chicken.

GENERAL WARNINGS

Veterinary surgeon should be consulted before the application and in case of any adverse effects. Keep out of reach of children.

PRECAUTIONS TO BE TAKEN BY THE APPLICATOR AND WARNINGS FOR THE SURGEONS

In case of contact with skin and eyes, wash your skin and eyes with plenty of water. Wash your hands following application. The people who are sensitive to quinolons should avoid contact with the drug. The applicator should avoid eating or drinking during application.

STORAGE CONDITIONS AND SHELF LIFE

Store at room temperature (15 – 25 oC). Protect from light.
The shelf life is 2 years from the date of manufacture.

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

The drug is put on the market in 100, 500, 1000, 2500 and 5000ml white colored, plastic packages which are of high density polypropilene.

SELLING AREA AND CONDITIONS

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

APPROVAL DATE OF PACKAGE INSERT

19.12.2005

DATE AND NUMBER OF THE MINISTRY OF AGRICULTURE AND RURAL AFFAIRS AUTHORIZATION

28.11.2005 – 15/032

NAME AND ADDRESS OF MARKETING AUTHORIZATION OWNER:

Alke Sağlik Ürünleri San. ve Tic. A.Ş

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

NAME AND ADDRESS OF MANUFACTURER COMPANY:

Alke Sağlik Ürünleri San. ve Tic. A.Ş

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

BATCH NO

DATE OF PRODUCTION

EXPIRY DATE

RESALE PRICE (VAT INCLUDED)