PELANGI DAIRY PRODUCT SDN. BHD. (665097-K)
No 46, Lorong Kendi 7, Taman Merak Jaya, 14100 Simpang Ampat,
S.P.S., Pulau Pinang, Malaysia.

PRODUCT LITERATURE

ENROMYCIN SOLUTION

Each ml contains
Enrofloxacin USP 100 mg

Preservatives
Methyl Paraben BP 0.15%
Propyl Paraben BP 0.015%

Mode of Administration
Orally administration

Pharmacodynamic
Enrofloxacin is a bactericidal agent. The bactericidal activity of enroflaxacin is concentration dependent, with susceptible bacteria cell death occurring within 20-30 minutes of exposure. It has demonstrated a significant post-antibiotic effect for both gram negative and positive bacteria and is active in both stationary and growth phases of bacterial replication. It's mechanism of action is not thoroughly understood, but it believed to act by inhibiting bacterial DNA-gyrase (a type II topoisomerase) thereby preventing DNA super coiling and DNA synthesis. Enfloxacin have good activity against many gram negative bacilli and cocci including most speices and strains of *Pseudomonas aeruginose, Klebsiella spp, E-coli, Enterobacter, Campylobacter, Shigella, Salmonella, Aeromonas, Haemophilus, Proteus, Yersinia, Serratia and Vibrio species.*These drugs have weak activity against most anaerobes and are ineffective in treating anaerobic infections.

Pharmacokinetic
Enrofloxacin is well absorbed after oral administration in most species. In dogs, enrofloxacin's bioavailability is approximately 80 %. The presence of food in the stomach may delay the rate, but not the extent of absorption. It is distributed throughout the body, in dogs the volume of distribution is approximately 3-4 L/kg and only about 27 % is bound to canin plasma proteins. Highest concentrations are found in the bile, kidney, liver, lungs and reproductive system (including prostatic fluid and tissue). Enrofloxacin reportedly concentrates in macrophages. Therapeutic levels are also attained in bones, synovial fluid, skin, muscle, aqueous humour and pleural fluid. Low concentrations are found in the CSF, and levels may only reach 6-10 % of those found in the serum. Enrofloxacin is metabolized to various metabolites, most of which are less active than the parent compounds. Enrofloxacin is eliminated via both renal and non renal mechanisms. Approximately 15-50 % of the drug is eliminated unchanged into the urine, by both tubular secretion and glomerullar filtration. The approximate elimination ½ lives in various species are dogs : 4-5 hours and cats : 6 hours.

Indication

For control and treatment of Infections caused by microorganisms sensitive to Enrofloxacin in poultry, cattle, pig and companion animals.

Contra-indication

Enroflaxacin is contraindicated in dogs during the rapid growth phase and not be used in dogs under 1 year of age. Should not be used in cats less than 12 weeks of age. Contraindicated in animals hypersensitive to enroflaxacin.

Warning /Precaution

Animals should not be allowed to become dehydrated during therapy with Enrofloxacin. Animals with severe renal or hepatic impairment may require dosage adjustments to prevent drug accumulation. Enrofloxacin may cause CNS stimulation and should be used with caution in animals with seizures disorders. Enrofloxacin should not be used by human, it may cause hallucination, vivid dream and headache.

Drug Interaction

Sucralfate may inhibit absorption by bind to enrofloxacin. It prevent from entering the body. Thus should be given at least 2 hours apart if they are used together. Theophylline blood levels may be higher than usual if this medication is used concurrently with enrofloxacin. If enrofloxacin is used with cyclosporine, may exacerbate nephrotoxicity of cyclosporine. Antacids containing cations (Mg^{2+}, Al^{3+}, Ca^{2+}) may bind to enrofloxacin and prevent its absorption. Probenecid blocks tubular secretion of enrofloxacin and may increase its blood level and half life. Nitrofurantoin may antagonize the antimicrobial activity of the fluroquinolones and their concomitant use is not recommended. Synergism may occur, but it not predictable, against some bacteria (particularly *Pseudomonas aeruginosa* or other Enterobacteriaceae) with these compounds and aminoglycosides, 3rd generation cephalosporins agents and extended-spectrum penicillins. Enrofloxacin has minimal activity against strains of *Peptostreptococcus, Lactobacillus and Bacteroids fragilis.*

Pregnancy and Lactation

Fluoroquinolones are not generally recommended for use during pregnancy because of the risk of cartilage abnormalities in young animals unless the benefits of therapy clearly outweigh the risks. Safety in breeding, pregnant or lactating cats has not been established.

Side Effects /Adverse Reaction

<u>In dogs</u> :

Elevated hepatic enzymes, ataxia, seizures, depression, lethargy and nervousness. Hypersensitivity reactions or crystalluria could potentially occur.

<u>In cats</u> :

Vomiting, anorexia, elevated hepatic enzymes, diarrhea, ataxia, seizures, depression or lethargy, vocalization and aggression.

Dosage

For dogs and cats:

5 mg/kg bodyweight once on a day

Sign and Symptoms of Over Dosage

Sign and Symptoms:

Dogs :

Vomiting and anorexia

Cats :

Ocular toxicity characterized by mydriasis, retinal degeneration and blindness

Treatment:

Withdrawal of the drug will return to be normal. Significant improvement of clinical signs is observed following drug withdrawal

Packing

Packed in plastic container of 500 ml and 1 L

Pharmaceutical Precaution

Store below 30°C in a dry place, protected from light

Expiry date : 2 years from date of manufacture.

Name and Address of Manufacturer

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Malaysian Drug Registration No. : MAL