VET'S CARE LINE

ENROLOX 50MG PALATABLE TABLETS

Description and Composition

ENROLOX 50MG PALATABLE TABLETS is an off-white to cream tablet, with score. Each tablet contains 50mg Enrofloxacin as its active ingredient.

Pharmacodynamics

Microbiology: Enrofloxacin, a 4-fluoroquinolone compound, is bactericidal with activity against a broad spectrum of both Gram-negative and Gram-positive bacteria. Fluoroquinolones elicit their bactericidal properties through interactions with two intercellular enzymes - DNA gyrase (DNA topoisomerase II) and DNA topoisomerase IV - which are essential for bacterial DNA transcription, synthesis and replication. It is believed that fluoroquinolones actively bind with DNA:ENZYME complexes and thereby inhibit the essential processes catalysed by the enzymes (DNA supercoiling and chromosomal decatenation). The ultimate outcome of fluoroquinolone intervention is DNA fragmentation and bacterial cell death.
Distribution in the body: Enrofloxacin penetrates into all canine and feline tissues and body fluids.

Pharmacokinetics

In dogs, the absorption and elimination characteristics of the oral formulation are linear (plasma concentrations increase proportionally with dose) when enrofloxacin is administered at up to 11.5mg / kg, twice daily. Approximately 80% of the orally administered dose enters the systemic circulation unchanged. The eliminating organs, based on the drug's body clearance time, can readily remove the drug with no indication that the eliminating mechanisms are saturated. The primary route of excretion is via the urine. The absorption and elimination characteristics beyond this point are unknown. In cats, no oral absorption information is available at other than 2.5mg / kg, administered orally as a single dose. Saturable absorption and/or elimination processes may occur at greater doses. When saturation of the absorption process occurs, the plasma concentration of the active moiety will be less than predicted, based on the concept of dose proportionality.

Following an oral dose in dogs of 2.5mg / kg (1.13mg / lb), enrofloxacin reached 50% of its maximum serum concentration in 15 minutes and peak serum level was reached in one hour. The elimination half-life in dogs is approximately 2 ½ - 3 hours at that dose, while in cats it is greater than 4 hours.

Indication

Dogs: For the treatment of dermal infections (wounds and abscesses) associated with susceptible strains of *Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis*, and *Staphylococcus intermedius*; respiratory infections (pneumonia, tonsillitis, rhinitis) associated with susceptible strains of *Escherichia coli* and *Staphylococcus aureus*; and urinary cystitis associated with susceptible strains of *Escherichia coli, Proteus mirabilis*, and *Staphylococcus aureus.*

Cats: For the treatment of dermal infections (wounds and abscesses) associated with susceptible strains of *Pasteurella multocida, Staphylococcus aureus*, and *Staphylococcus epidermidis*.

Recommended Dose

Dogs: 5mg to 20mg / kg body weight, either as a single dose or divided into 2 equal daily doses administered at 12-hour intervals. Selection of a dose within this range should be based on clinical experience, the severity of disease, and susceptibility of the pathogen.

Animals which receive doses in the upper end of the dose range should be carefully monitored for clinical signs that may include inappetence, depression, and vomiting.

Cats: 5mg / kg body weight, either as a single dose or divided into 2 equal daily doses administered at 12-hour intervals. In rare instances, use of this product in cats has been associated with retinal toxicity. Based

on post approval experience, cats should be carefully monitored for clinical signs of mydriasis and/or changes in the retina.

Dogs and cats: The duration of treatment should be selected based on clinical evidence. Generally, administration of the product should continue for at least 2 - 3 days beyond cessation of clinical signs. For severe and/or complicated infections, more prolonged therapy, up to 30 days, may be required. If no improvement is seen within five days, the diagnosis should be reevaluated, and a different course of therapy considered.

If necessary, the tablets may be offered to dogs in food or hand-administered (pilled). In cats, this product should be pilled.

Route of Administration
To be given by oral administration in cats and dogs.

Contraindications
Enrofloxacin is contraindicated in dogs and cats known to be hypersensitive to quinolones.
Dogs: The use of enrofloxacin is contraindicated in small and medium breeds of dogs during the rapid growth phase (between 2 and 8 months of age). The safe use of enrofloxacin has not been established in large and giant breeds during the rapid growth phase. Large breeds may be in this phase for up to one year of age and the giant breeds for up to 18 months. In clinical field trials utilizing a daily oral dose of 5.0mg / kg, there were no reports of lameness or joint problems in any breed. However, controlled studies with histological examination of the articular cartilage have not been conducted in the large or giant breeds.

Warning and Precautions
Special warnings for each target species
To limit the development of antimicrobial resistance:
- fluoroquinolone drugs should not be used indiscriminately.
- the product should not be used in food producing animals.

Special precautions for use
Special precautions for use in animals
Quinolone-class drugs should be used with caution in animals with known or suspected Central Nervous System (CNS) disorders. In such animals, quinolones have, in rare instances, been associated with CNS stimulation which may lead to convulsive seizures.
Quinolone-class drugs have been associated with cartilage erosions in weight-bearing joints and other forms of arthropathy in immature animals of various species. In rare instances, use of this product in cats has been associated with retinal toxicity. Safety in breeding or pregnant cats has not been established.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Keep out of reach of children.

Interactions with Other Medicaments
Compounds that contain metal cations (e.g., aluminium, calcium, iron, magnesium) may reduce the absorption of some quinolone-class drugs from the intestinal tract. Concomitant therapy with other drugs that are metabolized in the liver may reduce the clearance rates of the quinolone and the other drug.
Dogs: Enrofloxacin has been administered to dogs at a daily dosage rate of 10mg / kg concurrently with a wide variety of other health products including anthelmintics (praziquantel, febantel, sodium disophenol), insecticides (fenthion, pyrethrins), heartworm preventatives (diethylcarbamazine) and other antibiotics (ampicillin, gentamicin sulphate, penicillin, dihydrostreptomycin). No incompatibilities with other drugs are known at this time.
Cats: Enrofloxacin was administered at a daily dosage rate of 5mg / kg concurrently with anthelmintics (praziquantel, febantel), an insecticide (propoxur) and another antibacterial (ampicillin). No incompatibilities with other drugs are known at this time.

Pregnancy and Lactation
No adverse effects were observed on reproductive parameters when male dogs received 10 consecutive daily treatments of 15mg / kg / day at 3 intervals (90, 45 and 14 days) prior to breeding or when female dogs received 10 consecutive daily treatments of 15mg / kg / day at 4 intervals; between 30 and 0 days prior to breeding, early pregnancy (between 10th and 30th days), late pregnancy (between 40th and 60th days), and during lactation (the first 28 days). Safety in breeding or pregnant cats has not been established.

Side Effects
Dogs: The categories of reactions are listed in decreasing order of frequency by body system.

- Gastrointestinal: Anorexia, diarrhoea, vomiting, elevated liver enzymes
- Neurologic: Ataxia, seizures
- Behavioural: Depression, lethargy, nervousness

Cats: The categories of reactions are listed in decreasing order of frequency by body system.

- Ocular: Loss of vision, retinal abnormalities (retinal degeneration, retinal atrophy, attenuated retinal vessels, and hyperreflective tapeta have been reported), mydriasis
- Gastrointestinal: Vomiting, anorexia, elevated liver enzymes, diarrhoea
- Neurologic: Ataxia, seizures
- Behavioural: Depression, lethargy, vocalization, aggression

Symptoms and Treatment of Overdose
Do not exceed the recommended doses. In case of accidental overdose, gastrointestinal disorders (vomiting, diarrhoea and hypersalivation) or nervous signs (mydriasis, ataxia) may appear. In severe cases it may be necessary to interrupt treatment.
In cats, adverse ocular effects have been observed at doses higher than those recommended.
At doses equal to or greater than 20mg / kg body weight / day, toxic effects on the retina could lead to irreversible blindness in the cat.

Storage Condition
Store below 30ºC. Protect from light.

Shelf life
3 years.

Packing
30, 60, 100, 120, 200, 500 tablets.

Manufacturer & Product Registration Holder
Range Pharma Sdn Bhd
No. 1, Jalan TSB 11, Taman Industri Sg. Buloh, 47000 Sg. Buloh, Selangor Darul Ehsan, Malaysia
Tel: 603-61568708 Fax: 603-61568707
Email: support@vetscareline.com

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