VET'S CARE LINE

ENROLOX 15MG PALATABLE TABLETS

Description and Composition

ENROLOX 15MG PALATABLE TABLETS is an off-white to cream tablet, with score. Each tablet contains 15mg Enrofloxacin as its active ingredient.

Pharmacodynamics

Enrofloxacin is bactericidal in action with activity against Gram-positive and Gram-negative bacteria and mycoplasmas. The mechanism of action of the quinolones is unique among antimicrobials – they act primarily to inhibit bacterial DNA gyrase, an enzyme responsible for controlling the super coiling of bacterial DNA during replication. Resealing of the double standard helix is inhibited resulting in irreversible degradation of the chromosomal DNA. The fluoroquinolones also possess activity against bacteria in the stationary phase by an alteration of the permeability of the outer membrane phospholipid cell wall.

Susceptibility of selected target pathogens (MIC) is as follows:

- *Pasteurella multocida*: 0.03mg / L;
- *Escherichia coli*: 0.03 - 0.06mg / L;
- *Staphylococcus pseudointermedius*: 0.125mg / L;
- *Pseudomonas aeruginosa*: 2.0mg / L.

Susceptibility breakpoints are: sensitive ≤ 0.5mg / L; intermediate 1 - 2mg / L; resistant ≥ 4mg / L.

Bacterial resistance to fluoroquinolones most commonly occurs by alteration of the target, DNA-gyrase, via mutation. Less commonly mutation occurs at the topoisomerase-IV target. Other mechanisms of resistance occur when bacteria decrease the ability of the drug to enter the cell or increase active transport out of the cell. Resistance is usually chromosomally developed and, therefore, remains after antimicrobial therapy ends. Cross-resistance of enrofloxacin with other fluoroquinolones can occur. Changes in levels of resistance to fluoroquinolones over time by *Campylobacter* and *Salmonella* species are being monitored because of their possible impact on human health.

Pharmacokinetics

The pharmacokinetics of enrofloxacin in dogs and cats are such that oral and parenteral administration leads to similar serum levels.

Enrofloxacin is rapidly absorbed after oral, intramuscular and subcutaneous administration. In the study performed with the product in cats, the dose of enrofloxacin administered in cats was 3.36 (±0.30)mg / kg. The corrected maximal plasma concentration was 1654.37 ± 247.92ng / mL and it was reached within 1.28 (±0.58)h (Tmax). AUC was 8433.55 (±1851.80)ng / h / mL and the value of T1/2 was 3.75h (harmonic mean).

Approximately 40% of the oral or intravenous enrofloxacin dose administered in dogs is metabolized to ciprofloxacin. Maximal plasma concentration for ciprofloxacin in cats was 173.18 ± 34.08ng / mL. Tmax was 2.42 ± 0.89h and terminal half-life was 4.88h (harmonic mean).

Enrofloxacin possesses a high distribution volume. Tissue levels 2-3 times higher than that found in the serum, have been demonstrated in laboratory animals and target species. Organs in which high levels can be expected are lungs, liver, kidney, skin, bone and lymphatic system. Enrofloxacin also distributes into the cerebrospinal fluid, the aqueous humour and the foetus in pregnant animals. The elimination of enrofloxacin is renal, primarily through glomerular filtration and tubular secretion.

Indication
For the treatment of bacterial infections of the alimentary, respiratory and urogenital tracts, skin, secondary wound infections and otitis externa where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice in cats and dogs.

Recommended Dose
The dosage rate of enrofloxacin is 5mg / kg given orally once daily or as a divided dose twice daily for 5 to 10 days with or without food. Do not exceed the recommended dosage.

The daily dose is achieved as follows:
Cats and small dogs: One tablet per 3kg body weight.

The duration of treatment in dogs may be extended depending on the clinical response and the judgement of the responsible veterinary surgeon.

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

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

Contraindications
Do not use in dogs less than 1 year of age or in exceptionally large breeds of dog with a longer growth period less than 18 months of age, as articular cartilage may be affected during the period of rapid growth.
Do not use in cats less than 8 weeks of age.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in dogs having seizure disorders, since enrofloxacin may cause CNS stimulation.
Do not use for prophylaxis.

Warning and Precautions
Special warnings for each target species
None.

Special precautions for use
Special precautions for use in animals
Fluoroquinolones should be reserved for the treatment of clinical conditions which have responded poorly or are expected to respond poorly to other classes of antimicrobials.
Whenever possible, use of fluoroquinolones should be based on susceptibility testing. Use of the product deviating from the instructions given may increase the prevalence of bacteria resistant to the fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross-resistance.
Official and local antimicrobial policies should be taken into account when the product is used.
Do not use in case of resistance to quinolones, as there exists almost complete cross resistance to other quinolones and complete cross resistance to other fluoroquinolones.
Do not exceed the recommended dosage.
Retinotoxic effects including blindness can occur in cat when the recommended dose is exceeded.
Use the product with caution in dogs with severe renal or hepatic impairment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Wash hands after use.
In case of contact with the eyes, wash with plenty of clean water. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
People with known hypersensitivity to (fluoro)quinolones should avoid contact with the product.

Interactions with Other Medicaments
Do not combine with tetracyclines, phenicol or macrolides because of potential antagonistic effects.

Concurrent administration of fluoroquinolones may increase the action of oral anticoagulants.
Do not combine with theophylline as this could lead to a prolonged elimination of this substance.
Concurrent administration of magnesium or aluminium containing substances may be followed by retarded absorption of enrofloxacin.

Pregnancy and Lactation
As enrofloxacin passes into maternal milk, use only according to the benefit/risk assessment by the responsible veterinarian.

Side Effects
During the period of rapid growth, enrofloxacin may affect articular cartilage development.
In very rare cases (less than 1 animal in 10,000 animals, including isolated reports) vomiting and anorexia are observed.

Symptoms and Treatment of Overdose
In accidental overdose, vomiting, diarrhoea and CNS/behavioural changes may occur.
There is no antidote and treatment should be symptomatic. If necessary, administration of aluminium- or magnesium-containing antacids or activated carbon can be used to reduce absorption of enrofloxacin.
In target animal species, cats have been shown to suffer ocular damage after receiving doses of more than 15mg / kg once daily for 21 consecutive days. Doses of 30mg / kg given once daily for 21 consecutive days have been shown to cause irreversible ocular damage. At 50mg / kg given once daily for 21 consecutive days, blindness can occur.

Storage Condition
Store below 30ºC. Protect from light.

Shelf life
3 years.

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

Manufacturer & Product Registration Holder
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