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Enrox Flavour Tablets for Cats and Dogs

Species: Cats, Dogs

Therapeutic indication:Pharmaceuticals: Antimicrobials: Oral preparations: Tablets

Active ingredient: Enrofloxacin

Product: Enrox Flavour Tablets for Cats & Dogs

Product index: Enrox Flavour Tablets for Cats & Dogs

Incorporating: Enrox Flavour Tablets (15mg) for Cats & Dogs

Enrox Flavour Tablets (50mg) for Dogs

Enrox Flavour Tablets (150mg) for Dogs

Presentation

Round, slightly biconvex, cream to light brownish tablets with possible visible white or darker spots and bevel-edged.

Enrox Flavour Tablets	15mg	50n
Enrofloxacin(mg)	15	50
Species	Cats/Dogs	Dog

50mg and 150mg tablets can be divided into halves.

Uses

Enrox Flavour Tablets 15mg/kg is for use in dogs and cats.

NOAH Compendium

Enrox Flavour Tablets 50mg and 150mg/kg are for use in dogs only.

All three indicated 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.

Dosage and administration

FOR ORAL ADMINISTRATION.

DO NOT EXCEED RECOMMENDED DOSE.

5mg enrofloxacin per kg bodyweight per day. Given orally once daily or as a divided dose twice daily for 5 to 10 days with or without food.

Daily dose achieved as follows:

Cats and small dogs =	1 Enrox Flavour Tablet 15mg per 3kg bodyweight
Medium dogs =	1 Enrox Flavour Tablet 50mg per 10kg bodyweight
Large dogs =	1 Enrox Flavour Tablet 150mg per 30kg bodyweight

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.

Use during pregnancy and lactation

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

Contra-indications, warnings, etc

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.

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 15 mg/kg once daily for 21 consecutive days. Doses of 30 mg/kg given once daily for 21 consecutive days have been shown to cause irreversible ocular damage. At 50 mg/kg given once daily for 21 consecutive days, blindness can occur.

Interactions

Do not combine with tetracyclines, phenicols 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 aluminum containing substances may be followed by retarded absorption of enrofloxacin.

Special precautions for safe 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 in the SPC 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.

Cats - Retinotoxic effects including blindness can occur in cat when the recommended dose is exceeded.

Dogs - 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.

Adverse reactions (frequency and seriousness)

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

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

Pharmaceutical precautions

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years

Return any halved tablet to the opened strip-pack and use within 24 hours.

No special storage conditions required.

Legal category

Legal category:POM-V

Packaging quantities

Aluminium blisters of 10 tablets. Packaged into a cardboard box of 100 tablets.

Marketing Authorisation Holder (if different from distributor)

KRKA, d.d., Novo mesto

Šmarješka cesta 6

8501 Novo mesto

Slovenia

Further information

Pharmacotherapeutic group: Antibacterials for systemic use, quinolone and quinoxaline antibacterials, fluoroquinolones.

ATCvet code: QJ01MA90

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*: 0.03 mg/L;

-*Escherichia coli*: 0.03-0.06 mg/L;

-*Staphylococcus pseudointermedius*: 0.125 mg/L;

-*Pseudomonas aeruginosa*: 2.0 mg/L.

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

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 3.75 h (harmonic mean).

Approximately 40% of the oral or intravenous enrofloxacin dose administered in dogs is metabolised to ciprofloxacin.

Maximal plasma concentration for ciprofloxacin in cats was 173.18±34.08 ng/mL. T max was 2.42±0.89 h and terminal half life was 4.88 h (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.

Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater. Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local

requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

Marketing Authorisation Number

Enrox Flavour Tablets for Cats & Dogs 15mg

Enrox Flavour Tablets for Dogs 50mg

Enrox Flavour Tablets for Dogs 150mg

Significant changes

GTIN

GTIN description: Enrox Flavour (15mg) Tablets for Cats and Dogs 100 tablet pack

GTIN:03838989656379

GTIN description: Enrox Flavour (50mg) Tablets for Dogs 100 tablet pack

GTIN:03838989656393

GTIN description: Enrox Flavour (150mg) Tablets for Dogs 100 tablet pack

GTIN:03838989656386