

Colmyc-E 10% Oral Solution

Oral solution



Composition

Enrofloxacin..... 10 g
Excipient to.....100 ml

Product description

Antibacterial for veterinary use.

Pharmacodynamic properties

Enrofloxacin is a synthetic, broad spectrum antimicrobial substance, belonging to the fluoroquinolone group of antibiotics. It is bactericidal in action by a concentration-dependant killing activity against many 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 supercoiling of bacterial DNA during replication. Resealing of the double stranded 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.

Pharmacokinetic properties

The pharmacokinetics of enrofloxacin are such that oral and parenteral administration leads to similar serum levels. Enrofloxacin possesses a high distribution volume. Tissue levels 2-3 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 the lungs, liver, kidney, bone and lymphatic system.

Enrofloxacin also distributes into the cerebrospinal fluid, the aqueous humour and the foetus in pregnant animals.

Environmental properties

Not applicable.

Indications

For the use in the treatment of infections due to *Escherichia coli* or/and *Mycoplasma gallisepticum* where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice.

Target species

Poultry: Chickens and turkeys.

Recommended dosage

For oral administration via the drinking water. This may be put directly into the header tanks, or via water proportioner systems.

Dosage: 10 mg of enrofloxacin per kg bodyweight per day for five consecutive days.

Medication of the water supply should be continuous during the treatment period and no other source of water should be available. Medicated water should be made every day, immediately prior to provision.

Route of administration

For oral administration via the drinking water. This may be put directly into the header tanks, or via water proportioner systems.

Contraindications

The product should not be used for prophylaxis

Warnings and precautions

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, fluoroquinolones should only be used based on susceptibility testing.

Use of the product deviating from the instructions given in this product 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.

Interactions with other medicinal products

When combined with tetracyclines and macrolide antibiotics, enrofloxacin may produce an antagonistic effect. Resorption of enrofloxacin may be reduced, when it is combined with substances containing magnesium or aluminium. The serum level of theophylline may increase when it is combined with enrofloxacin. Do not combine enrofloxacin with non steroidal antiphlogistics. Increased influx of the air (admixing CO₂ from the air) into medicated drinking water may result in precipitation of enrofloxacin.

Precipitation of the salt of enrofloxacin and alkalis may occur at higher concentration of calcium and magnesium in the water system during intermediate dilution in the dosage devices.

Use during pregnancy and lactation

Not applicable, the product is indicated only for use in poultry.

Lay: Do not administer to layer replacement birds within 14 days of coming into lay.

Side effects (frequency and severity)

With a very low incidence, gastrointestinal effects (nausea, vomit and anorexia) can appear, and alterations of the nervous system (vertigo, cephalgia) and also haematological and enzymatic alterations.

Symptoms and treatment of overdose

Gastrointestinal and nervous system alterations can appear in case of overdose. In case of overdose, eliminate the medication and apply the symptomatic treatment.

Storage conditions

Store in a cool (under 25°C.), dry place protected from intensive light.

Withdrawal period

Meat and offal: Chickens: 4 days.

Turkeys: 4 days.

Do not use in birds producing eggs for human consumption.

Proposed shelf life (as package for sale)

2 years.

Proposed shelf life (after first opening of the container)

28 days.

Proposed shelf life (after reconstitution or dilution)

48 hours in medicated water.

Presentations

1 lt and 5 lt.

Date of revision of package insert

16th November 2011.



Manufactured by:

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