

E-10 Oral Solution

E-10 appears to be a light yellow solution packed in HDPE plastic screw necked bottle and seal with a PET / PE / Aluminium foil / PE / LLDPE.

Composition:

Each Litre contains

Enrofloxacin 100 g

Pharmacodynamics:

Enrofloxacin inhibits bacterial DNA gyrase or topoisomerase IV (a type II topoisomerase), thereby preventing DNA supercoiling and replication. Cell respiration and division end, and other processes are interrupted, including membrane integrity. It enters cells via porins and accumulates rapidly in susceptible bacteria.

Pharmacokinetics:

Oral absorption of fluoroquinolones is high for most animals studied. It is not affected by administration with food, although absorption may be delayed. Divalent and trivalent cations can affect absorption. In cats, dogs, and pigs, oral absorption of fluoroquinolones approaches 100%, but in ruminants, it is generally less. However, enrofloxacin is rapidly absorbed in monogastric species and preruminant calves. Absorption in adult ruminants is variable and has ranged from 10 to 50%. Fluoroquinolones achieve concentrations that are at least as high as plasma in a wide range of tissues, with the exception of the central nervous system and the eye. This includes cats, cattle, chickens, dogs, horses, pigs, and rabbits. Fluoroquinolones are rapidly accumulated in macrophages and neutrophils. Unlike other antibiotics that concentrate in subcellular sites within phagocytic cells, the quinolones are distributed into the cytosol where they can reach intracellular pathogens. This concentration in leukocytes may explain the higher fluoroquinolone concentrations in infected tissue compared to healthy tissue.

Enrofloxacin is de-ethylated to form ciprofloxacin, an antimicrobically active metabolite in many species. In lactating cattle, the serum concentration of ciprofloxacin is 35% that of enrofloxacin during the elimination phase, after an intravenous dose of 5 mg/kg. In chickens, enrofloxacin is extensively metabolized to ciprofloxacin. In ducks, less than 10% of the administered enrofloxacin dose is converted to ciprofloxacin after a 10 mg/kg dose. The concentration of ciprofloxacin in the serum reaches 20 to 35% of the enrofloxacin concentration in adult horses. In foals, the amount of ciprofloxacin measured is negligible. In pigs, the concentration of ciprofloxacin in the plasma comprises less than 10% of the amount of enrofloxacin present in the plasma. Enrofloxacin is eliminated through renal, primarily by glomerular filtration and tubular secretion.

Indications:

Poultry: It is for the treatment and CCRD (Complicated Chronic Respiratory Disease), E.coli infections, Salmonellosis, Pasteurellosis and other respiratory diseases.

Directions for Use:

The product is administered via the drinking water. Medicated water should be made up immediately prior to provision. Medication of the water supply should be continuous during the treatment period and no other source of water should be available. The product should be given over a minimum period of 6 hours per day to allow all birds to drink. The dose rate is 10 mg/kg bodyweight daily for 3 to 10 days.

Each ml contains 100 mg enrofloxacin. Calculate the daily quantity (ml) of E-10 Oral Solution required for treatment period as follows :

Total number of birds x Average body weight in kg x 0.1 = Total volume (ml) per day

E-10 Oral Solution may be put directly into the header tank or introduced via a water proportioner pump. For the treatment of salmonellosis or

Warning and Precautions:

Risk of increasing resistance of human pathogens to fluoroquinolones as well as the ability of infections in animals to resist treatment should be considered by health practitioners when prescribing these medications. It is not recommended to treat birds producing eggs for human consumption. Do not use for prophylaxis

Interactions with Other Medicaments:

The following drug interaction and related problems have been selected on the basis of potential clinical significance. Antacids, aluminum-, calcium-, or magnesium-containing or laxatives, magnesium-containing or multivitamins or sucralfate or zinc. Compounds contain divalent or trivalent cations, such as aluminum, calcium, iron, magnesium, or zinc, administered concurrently with a fluoroquinolone, may reduce the absorption of the fluoroquinolone. It should not be administered with non-steroidal anti-inflammation drugs (NSAIDs).

Statement on Usage During Pregnancy and Lactation:

The attributes of fluoroquinolones make them likely to cross the placenta in many species; however, adverse effects have not yet been reported when fluoroquinolones have been administered to pregnant animals. In Cats and cattle, effect on reproduction or pregnancy has not been established. In chickens, no adverse effects were noted in measured reproductive parameters when male and female chickens were given an enrofloxacin dose of 150 parts per million in the drinking water for 7 days. This regimen was repeated at five different ages between 1 day and 206 days of age with no reproductive effect noted. The parameters measured included egg production, egg weight, hatchability, chick viability, and reproductive histology of treated birds and their hatched chicks. Because of the risk of producing arthropathies in immature animals, it has been recommended that significant levels of fluoroquinolones in the milk of nursing animals be avoided. Fluoroquinolones can be distributed into milk, sometimes at a higher concentration than in plasma, but it is not known under what conditions significant amounts might be absorbed by nursing animals.

Overdose and Treatment::

There is reported lethal dose in turkey and poultry, 1-day-old: Oral—626 parts of enrofloxacin per million parts of drinking water administered for 21 days caused the death of 11 out of 40 birds in the first 10 days. Surviving birds showed signs of listlessness and decreased body weight gain.

Clinical effects of overdose is also seen in chicks, 1-day-old, with a dose in drinking water of 625 ppm for 21 to 28 days. The effects are decreased in water consumption and decreased in weight.

In calves, a dose of 15 or 25 mg/kg a day for 10 to 15 days or a dose of 50 mg/kg a day for 3 days can lead to clinical effects of depression, decreased in appetite, incoordination and muscle fasciculation.

Although there is no specific information available on treatment of fluoroquinolone overdose in animals, treatment of human overdose includes induction of vomiting or use of gastric lavage, observation, and supportive care, including hydration and dialysis. Do not exceed recommended dose.

Withdrawal Period (s): 14 days.

Storage Condition:

Store below 30°C. Protect from sunlight and heat exposure.

Shelf-life after opening: 28 days.

Shelf life after reconstitution: 24 hours.

Presentation: 1L.

pasteurellosis a treatment period of 5 to 10 days must be used. For other conditions the duration of treatment may be 3 to 5 days

Mode of Administration: Oral Solution.

Contraindication:

The medical contraindications have been selected on the basis of the potential significance. This medication should not be used if there is hypersensitivity of animals to quinolones. It is also not recommended in immature animals in some species. (Fluoroquinolone administration during rapid growth has been associated with arthropathies and cartilage erosions in weight bearing joints in immature cats, dogs, and horses. Do not use in chickens producing eggs for human consumption.

Adverse Effects /Undesirable Effects:

The stated side effects have been selected on the basis of potential clinical significance. Arthropathy is seen in immature animals, especially dogs and foals. Cartilage damage has been observed in some cats. Ataxia is also seen in cats and dogs.

Packaging Available: 1 L.

Name and Address of Manufacturer:

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