ENROFIN INPEL 10%

BROAD-SPECTRUM ANTIBIOTIC

INJECTABLE SOLUTION

Health Registration No.:2C1-11875 - AGROCALIDAD

Formula:

Each 1 mL contains:

Enrofloxacin	100 mg
Excipients q.s.	1 ml

SPECIES AND DOSAGE:



DOSAGE
ROUTE OF ADMINISTRATION:
Parenteral.

The duration of treatment, dosage, and frequency of administration of the product may be modified at the discretion of the veterinarian.

Species	Reference Dose	Practical Dose	Indications
Cattle	7.5–12.5 mg/kg	10 mL/100 kg	Administer a single dose by subcutaneous route.
Cattle	2.5–5 mg/kg	2.5–5 mL/100 kg	Administer every 24 h for 3–5 days by subcutaneous route.
Swine	7.5 mg/kg	3 mL/40 kg	Administer a single dose by subcutaneous route.
Swine	2.5–5 mg/kg	2.5–5 mL/100 kg	Administer every 24 h for 3–5 days by subcutaneous route.

DOSAGE
ROUTE OF ADMINISTRATION:
Parenteral.

The duration of treatment, dosage, and frequency of administration of the product may be modified at the discretion of the veterinarian.

Species	Reference Dose	Practical Dose	Indications
Equine	5 mg/kg	5 mL/100 kg	Administer every 24 h by intramuscular route.
Canine	5 mg/kg	0.5 mL/10 kg	Administer every 24 h by subcutaneous or intramuscular route.
Feline	5 mg/kg	0.25 mL/5 kg	Administer every 24 h by subcutaneous or intramuscular route.

INDICATIONS

Indicated for the control and treatment of skin, soft tissue, and urinary tract infections caused by bacteria susceptible to enrofloxacin. Indicated in cats for the treatment of Chlamydophila felis; in dogs for the treatment of ulcerative colitis caused by E. coli and Rickettsia spp.; in swine for the treatment and control of swine respiratory disease associated with Actinobacillus pleuropneumoniae, Pasteurella multocida, Haemophilus parasuis, and Streptococcus suis; and in cattle for the treatment of bovine respiratory disease associated with Mannheimia haemolytica, Pasteurella multocida, and Haemophilus somni; in horses, it is effective in the treatment of various soft tissue infections caused by susceptible Gram-negative and Gram-positive aerobic bacteria.

ROUTE OF ADMINISTRATION: Parenteral.

PHARMACOKINETICS

Due to its lipophilic nature and low affinity for plasma proteins, enrofloxacin is widely distributed in tissues. Concentrations ranging from 35 to 100% of the serum concentration can be found in skin and bone. Concentrations in bronchial secretions can be up to three times the serum concentration. This antibiotic penetrates the cerebrospinal fluid to approximately 25%. Additionally, enrofloxacin accumulates in phagocytic cells by simple diffusion.

Enrofloxacin is eliminated both renally and via non-renal mechanisms. Approximately 15–50% of the drug is excreted unchanged in the urine, via both tubular secretion and glomerular filtration.

The major metabolite of enrofloxacin is ciprofloxacin. Due to the dual route of elimination (renal and hepatic), patients with severe renal impairment may have a slightly prolonged half-life and higher serum levels, but no dose adjustment is required.

MECHANISM OF ACTION

Enrofloxacin is a concentration-dependent bactericidal agent. Death of susceptible bacteria occurs within 20 to 30 minutes after exposure.

It has a significant post-antibiotic effect on both Gram negative and Gram-positive bacteria and is active during both the stationary and growth phases of bacterial replication.

Its mechanism of action is believed to involve the inhibition of bacterial DNA gyrase (type II topoisomerase), thereby preventing the unwinding and synthesis of the DNA strand and, consequently, bacterial replication.

Both enrofloxacin and ciprofloxacin have a similar spectrum of activity. These agents are effective against many Gram-negative bacilli and cocci, including most species and strains of Pseudomonas aeruginosa, Klebsiella spp., E. coli, Enterobacter spp., Campylobacter spp., Shigella spp., Salmonella spp., ., Aeromonas spp., Haemophilus spp., Proteus spp., Yersinia spp., Serratia spp., and Vibrio spp. Other agents that are typically susceptible include Brucella spp., Chlamydia trachomatis, Staphylococcus spp. (including penicillinase-producing and methicillin resistant strains), Mycoplasma spp., and Mycobacterium spp. (not the causative agent of Johne's disease).

Fluoroquinolones have variable activity against most streptococci and are not generally recommended for these infections. These drugs have weak activity against most anaerobes and are ineffective in treating anaerobic infections.

PRECAUTIONS – WARNINGS - CONTRAINDICATIONS

Use in species other than those authorized is not recommended.

Do not administer to patients with hypersensitivity to the active ingredient.

Contraindicated in small- to medium-sized dog breeds between 2 and 8 months of age, as "bubble-like" changes have been observed in the articular cartilage. To prevent cartilage damage, large and giant breed dogs may need to wait longer than the recommended 8 months before receiving this medication, as they may still be in the growth phase.

Because ciprofloxacin has occasionally caused crystalluria in humans, animals should not be allowed to become dehydrated during treatment with ciprofloxacin or enrofloxacin.

Enrofloxacin may cause CNS stimulation and should be used with caution in patients with seizure disorders.

Patients with severe impairment of renal or hepatic function may require a dose adjustment to prevent

drug accumulation.

DRUG INTERACTIONS

Fluoroquinolones may exacerbate nephrotoxicity and reduce the metabolism of cyclosporine (when administered systemically).

In dogs, it has been observed that flunixin meglumine increases the area under the curve and the elimination half life of enrofloxacin, and enrofloxacin, in turn, increases the area under the curve and the elimination half-life of flunixin meglumine.

Co-administration with glibenclamide may cause severe hypoglycemia.

Co-administration with methotrexate may lead to increased levels of methotrexate and, consequently, toxicity issues.

Enrofloxacin/ciprofloxacin may alter phenytoin levels.

Enrofloxacin and ciprofloxacin may increase blood levels of theophylline.

Enrofloxacin may increase the effects of warfarin.

ADVERSE REACTIONS

With the exception of possible cartilage abnormalities in young animals, the adverse effect profile of enrofloxacin is generally limited to gastrointestinal disturbances (vomiting, anorexia).

In dogs, elevated liver enzymes, ataxia, seizures, depression, lethargy, and nervousness have been reported rarely. Hypersensitivity reactions or crystalluria may occur.

In cats, ocular toxicity has been reported in very few cases; this condition is characterized by mydriasis, retinal degeneration, and blindness. These effects were generally observed at high doses (> 15 mg/kg). Other rare adverse effects in cats may include: vomiting, anorexia, elevated liver enzymes, diarrhea, ataxia, seizures, depression/lethargy, vocalization, and aggression.

WITHDRAWAL

Pigs: 5 days
Beef cattle: 28 days
Do not use in animals intended for milk production.

COMMERCIAL PRESENTATIONS

10-ml bottle
50-ml bottle
100-ml bottle
250-ml bottle