Enroxsel-10
Injection

For Veterinary Use Only

COMPOSITION:
Each ml contains:
Enrofloxacin.....100 mg

PHARMACODYNAMIC PROPERTIES:
Enrofloxacin has a spectrum of activity which includes Enrofloxacin-sensitive Histophilus somni, Mannheimia haemolytica, Pasteurella multocida, Mycoplasma gallisepticum, Mycoplasma synovia, Avibacterium paragallinarum, Escherichia coli.
Enrofloxacin belongs to the fluoroquinolone group of antibiotics. The substance has bactericidal activity which is mediated by binding to subunit A of DNA gyrase and the resulting selective inhibition of this enzyme. DNA gyrase is a topoisomerase. These enzymes are involved in the replication, transcription and recombination of bacterial DNA. Fluoroquinolones also influence bacteria in the stationary phase by altering cell wall permeability.
Resistance to fluoroquinolones has been reported to arise from five sources, (i) point mutations in the genes encoding for DNA gyrase and/or
topoisomerase IV leading to alterations of the respective enzyme, (ii) alterations of drug permeability in Gram-negative bacteria, (iii) efflux mechanisms, (iv) plasmid mediated resistance and (v) gyrase protecting proteins. All mechanisms lead to a reduced susceptibility of the bacteria to fluoroquinolones. Cross-resistance within the fluoroquinolone class of antimicrobials is common.
The inhibitory and bactericidal concentrations of enrofloxacin are very close, being either identical or differing by no more than 1-2 dilution steps.

MIC-DATA:

Cattle: Species	Number of strains	MIC50 (µg/mL)	MIC90 (µg/mL)	Resistance (%)
Mannheimia haemolytica	82	0.03	0.06	0.0
Pasteurella multocida	105	0.008	0.03	1.0
Histophilus somni	41	0.03	0.03	0.0
Escherichia coli (mastitis)	163	0.03	0.06	n.a.
Mycoplasma bovis	58	0.19	0.25	n.a

PHARMACOKINETIC PARTICULARS:
Following subcutaneous administration of the product in cattle or intramuscular administration in pigs, the active ingredient, enrofloxacin, is absorbed very rapidly and almost completely (high bioavailability).
After subcutaneous administration at a dose rate of 7.5 mg enrofloxacin per kg body weight to non-lactating cattle peak plasma concentrations of 0.82 mg/L are reached within 5 hours. The overall drug exposure in plasma is 9.1mg hr/L. Enrofloxacin is eliminated from the body at a half-life of 6.4 hr. approximately 50% of enrofloxacin is metabolized to the active substance ciprofloxacin. Ciprofloxacin is eliminated from the body at a half-life of 6.8 hr.

INDICATIONS:
Enroxsel-10 injection is indicated for treatment of chronic respiratory disease (CRD) in poultry, hemorrhagic septicemia (HS) and bovine respiratory disease (BRD) and alimentary tract infections in cattle, buffalo, sheep and goats.

CONTRAINDICATIONS:
Do not use in the presence of documented hypersensitivity to the pharmacologically active ingredient. Do not use in animals with central nervous system-associated seizure disorders. Do not use in the presence of existing disorders of cartilage development or musculoskeletal damage around functionally significant or weight-bearing joints.

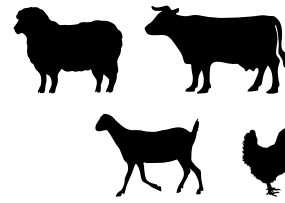
DOSAGE AND ADMINISTRATION:
Cattle / Buffalo / Sheep / Goats: 0.5-1ml per 20kg body weight by subcutaneous injection for 3-5 days.
Poultry: 0.1ml per kg body weight for 3-10 days.

SPECIAL PRECAUTIONS FOR USE IN ANIMALS:
For repeated injection or for injection volumes exceeding 15 ml (cattle) in divided doses, a new site must be chosen for each injection. Enrofloxacin is eliminated renally. As with all fluoroquinolones, delayed excretion can therefore be expected in the presence of existing renal damage.

SHELF LIFE:
Shelf life of the veterinary medicinal product in the unopened container: 2 years
Shelf life after first opening of the container: 28 days

SPECIAL PRECAUTIONS FOR STORAGE:
Keep out of the reach of children.
Store between 15-25°C in a cool and dry place.
Consult the Veterinarian before use only.

Innovator's Specs



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ISO CERTIFIED COMPANY