130*190

For Veterinary Use Only

Enrofloxacin 10% w/v injection

KENOXIN Injection

CONTENT : Each mL contains 100mg of Enrofloxacin.
Benzyl alcohol (as preservative)---------- 31.35mg/mL

PRODUCT DESCRIPTION : Pale yellowish to yellow liquid

PHARMACODYNAMICS :

Mode of action

Two enzymes essential in DNA replication and transcription, DNA gyrase and topoisomerase IV, have been identified as the molecular targets of fluoroquinolones. Target inhibition is caused by non-covalent binding of fluoroquinolone molecules to these enzymes. Replication forks and translational complexes cannot proceed beyond such enzyme-DNA-fluoroquinolone complexes, and inhibition of DNA and mRNA synthesis triggers events resulting in a rapid, drug concentration-dependent killing of pathogenic bacteria.
The mode of action of enrofloxacin is bactericidal and bactericidal activity is concentration dependent.

Antibacterial spectrum

Enrofloxacin is active against many Gram-negative bacteria such as *Escherichia coli, Klebsiella* spp., *Actinobacillus pleuropneumoniae*, *Mannheimia haemolytica, Pasteurella* spp. (e.g. *Pasteurella multocida*), against Gram-positive bacteria such as *Staphylococcus* spp. (e.g. *Staphylococcus aureus*) and against *Mycoplasma* spp. at the recommended therapeutic doses.

Types and mechanisms of resistance

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.

PHARMACOKINETICS :

Enrofloxacin is rapidly absorbed after parenteral injection. Bioavailability is high (approximately 100% in pig and cattle) with a low to moderate plasma protein binding (approximately 20 to 50%). Enrofloxacin is metabolized to the active substance ciprofloxacin at approximately 40% in ruminants and less than 10% in pigs. Enrofloxacin and ciprofloxacin distribute well into all target tissues, e.g. lung, kidney, skin and liver, reaching 2- to 3-fold higher concentrations than in plasma.
Parent substance and active metabolite are cleared from the body via urine and faeces.
Accumulation in plasma does not occur following a treatment interval of 24 h.
In milk, most of drug activity consists on ciprofloxacin. Overall drug concentrations peak at 2 hours after treatment showing an approximately 3-fold higher total exposure over the 24 hours dosing interval compared to plasma.

INDICATION :

For the treatment of bacterial disease susceptible to enrofloxacin.

Cattle :

Treatment of colibacillosis (diarrhea, sepsis and *E. coli*), mycoplasmosis (*Mycoplasma bovis*), salmonellosis (*Salmonella typhimurium*) and pneumonic pasteurellosis (*Pasteurella multocida* and *Pasteurella haemolytica*)

Swine :

Treatmeant of colibacillosis (diarrhea, sepsis and *E. coli*), mycoplasmal pneumonia (*Mycoplasma hyopneumoniae*), salmonellosis (*Salmonella typhimurium* and *Salmonella derby*), pneumonic pasteurellosis (*Pasteurella multocida*) and pleuro pneumonia (*Actinobacillus pleuropneumoniae*)

Dogs and Cats :

Treatment of urinary tract infection (*E. coli*) and wound infection

DOSAGE & ADMINISTRATION :

Method :

Cattle, Dogs and Cats – subcutaneous injection
Swine - intramuscular injection

Administration :

	Bacterial disease	Severe case of respiratory or digestive disease	Salmonellosis
Cattle and Swine	0.25mL of Kenoxin per 10kg of body weight per day for 3 days	0.5mL of Kenoxin per 10kg of body weight per day for 3~5 days	0.5mL of Kenoxin per 10kg of body weight per day for 5 days
Dogs and Cats	0.05mL of Kenoxin per 1kg of body weight per day for 5~10 days	–	–

CONTRAINDICATIONS :

Do not use on animals that have had shock or hypersensitivity reaction to this drug.
Do not administer to animals with hepatic impairment or renal impairment.
Do not use in young dogs (medium dogs less than 8 months, large dogs less than 12 months, very large dogs less than 18 months), because cartilage malformations can be caused.

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WARNINGS / PRECAUTIONS :

i. Special precautions for use in animals.

Do not mix any other drugs.
Shake well before use and use sterile syringe & needle to each animal.
Before use, keep the injection solution around 25℃.
Disinfect injection the site with 70% alcohol before injection to prevent suppuration or inflammation at injection site may occur.
Inject correctly to prevent pain, hardness and abscess at injection site.
If you are injected into animals weighing over than 200kg, divide them into two or more site.

ii. Special precautions to be taken by the person administering the veterinary medicinal product to animals.

Wear the protective equipment such as gloves, mask to avoid direct contact with skin and inhalation.
In case of contact with skin or eyes, rinse immediately with plenty of water and seek medical advice as soon as possible.
If you have any questions about the product, please contact the manufacturer or local retailer.

iii. Other precautions

Please follow to the prescribed storage method as it may lead to changes in effectiveness and stability.
Do not use products that have passed the expiration date and dispose them safely.
After opening, please use as soon as possible and keep the original packing containers sealed in a place where moisture and light rays are blocked.
Use by veterinarian's instruction, and veterinary use only.
This is drugs for animal use, so do not use the product for human.
Keep the recommended dosage and administration.
Keep the withdrawal period.
Keep out of reach of children and animals.
Since safety and effectiveness other than the designated livestock species has not been established, please do not use it arbitrarily.
Please observe the prescribed dosing capacity as it may cause economic loss, such as weakness caused by abuse and residue of livestock food.
Read instruction manuals completely before use.

DRUGS INTERACTIONS :

Do not use in combination with macrolides, tetracycline antibiotics.
Mixing with drug containing magnesium, aluminum, and calcium ions may inhibit absorption.
Co-administration with theophylline or caffeine may increase the concentration of theophylline or caffeine in the blood.
Probenecid may increase the concentration of enrofloxacin in the blood by preventing renal tubular discharge of this drug.
When used in combination with Cyclosporine it can exacerbate the renal toxicity of cyclosporine.
When used in combination with nonsteroidal anti-inflammatory drugs, convulsions may occur in rare cases.

PREGNANCY AND LACTATION :

Pregnant animals are prone to injection stress and should be administered with caution.

ADVERSE EFFECTS :

Joint problems (lacerations, pain, cartilage failure) may occur when they are administered to growing animals.
Gastrointestinal disorders (vomiting, loss of appetite, diarrhea, abdominal pain, etc.) may occur.
Do not use in animals that are epileptic or suffer from seizures since enrofloxacin may cause CNS stimulation.
May occur hypersensitivity reactions, and crystalline urine.

OVERDOSE AND TREATMENT :

Overdose (10 times or more) may cause abnormalities such as vomiting and decreased feeding.
Overdose to cats (> 15 mg / kg) may occur mydriasis and retinal degeneration.

STORAGE CONDITIONS : Store in a cool and dark place with dry condition to avoid moisture. Do not store above 30ºC.

PROPOSED SHELF LIFE AFTER FIRST OPENING : After opening, the product should be used immediately.

WITHDRAWAL PERIOD(S) :

Cattle : 20 days. (Milk: 4 days)
Swine : 20 days.

DOSAGE FORMS AND PACKAGING AVAILABLE : 100 mL transparent plastic bottle

DATE OF REVISION OF PACKAGE INSERT : 9 March 2021

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