

Veterinary Package Insert

TP-ENRO 200 SOL ENROFLOXACIN 200MG/ML SOLUTION (20% Enrofloxacin)

PRODUCT DESCRIPTION

TP-Enro 200 Sol Enrofloxacin 200mg/ml solution is a pale yellow or light yellow colour liquid, which contains 20% enrofloxacin, in 1 L bottle.

PHARMACODYNAMICS & PHARMACOKINETICS

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. They modulate the topological state of DNA through cleaving and resealing reactions. Initially, both strands of the DNA double helix are cleaved. Then, a distant segment of DNA is passed through this break before the strands are resealed. Target inhibition is caused by non-covalent binding of fluoroquinolone molecules to an intermediate state in this sequence of reactions, in which DNA is cleaved, but both strands are retained covalently attached to the 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-dependant killing of pathogenic bacteria.

Antibacterial spectrum

Enrofloxacin is active against many Gram-negative bacteria, against Gram-positive bacteria and *Mycoplasma* spp.

In vitro susceptibility has been shown in strains of (i) Gram-negative species such as *Escherichia coli*, *Pasteurella multocida* and *Avibacterium* (*Haemophilus*) *paragallinarum* and (ii) *Mycoplasma gallisepticum* and *Mycoplasma synoviae*.

Enrofloxacin administered via drinking water to poultry is rapidly and very well absorbed with a bioavailability of approx. 90 %. In poultry enrofloxacin is poorly metabolised to its active metabolite ciprofloxacin (approximately 5%). Enrofloxacin is eliminated from the body at a half-life of 6 hours. Protein binding in poultry is approximately 25%.

INDICATION

Treatment of the infections caused by the following bacteria susceptible to enrofloxacin:

Chickens

Mycoplasma gallisepticum,
Mycoplasma synoviae,
Avibacterium paragallinarum,
Pasteurella multocida,
Escherichia coli.

Turkey

Mycoplasma gallisepticum,
Mycoplasma synoviae,
Pasteurella multocida,
Escherichia coli.

RECOMMENDED DOSAGE AND ADMINISTRATION

Chickens and turkeys

10 mg enrofloxacin/kg bodyweight per day for 3-5 consecutive days.

Treatment for 3-5 consecutive days; for 5 consecutive days in mixed infections and chronic progressive forms. If no clinical improvement is achieved within 2-3 days, alternative antimicrobial therapy should be considered based on susceptibility testing.

Via the drinking water. Always make sure that the entire dose offered has been consumed. The medicated water should be made up fresh each day just before it is offered to the animals. The drinking water must be medicated throughout the treatment period, and no other water source should be available. Determine the bodyweight of the birds as accurately as possible in order to avoid underdosing.

Use only fresh pre-solutions, prepared every day before start of treatment. Pumping systems should be checked constantly to assure proper medication. Empty the water system and fill it with medicated water before starting the treatment.

Calculate the daily quantity (ml) of TP-Enro 200 Sol Enrofloxacin 200mg/ml Solution required for treatment period as follows:

Total number of birds x Average body weight in kg x 0.05 = Total volume (ml) per day

(Notes: 0.05ml of TP-Enro 200 Sol Enrofloxacin 200mg/ml Solution contains 10mg of enrofloxacin.)

CONTRAINDICATIONS

Do not use for prophylaxis.

Do not use when resistance/ cross-resistance to (fluoro)quinolones is known to occur in the flock intended for treatment .

Do not use in the case of known hypersensitivity to the active substance, other (fluoro)quinolones or to any of the excipients.

WARNINGS & PRECAUTIONS.

To be prescribed by registered veterinary surgeons only.

Special warnings for each target species

Treatment of *Mycoplasma* spp infections may not eradicate the organism.

Special precautions for use in animals

Official and local antimicrobial policies should be taken into account when the product is used.

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.

Since enrofloxacin was first authorised for use in poultry, there has been widespread reduction in susceptibility of *E.coli* to fluoroquinolones and emergence of resistant organisms.

Whenever possible, fluoroquinolones should only be used based on susceptibility testing.

Use of the product deviating from the instructions given here 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.

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

Those with known hypersensitivity to (fluoro)quinolones should avoid contact with this product.

Avoid contact with skin and eyes.

Rinse any splashes from skin or eyes immediately with water.

Wash hands and exposed skin after use.

Do not eat, drink or smoke while using the product.

INTERACTIONS WITH OTHER MEDICATIONS

In vitro, an antagonism was shown, when combining fluoroquinolones with bacteriostatic antimicrobial agents such as macrolides or tetracyclines and phenicols. The simultaneous application of substances containing aluminium or magnesium can impair the absorption of enrofloxacin.

PREGNANCY AND LACTATION

Do not use in laying hens producing eggs for human consumption.

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

ADVERSE EFFECTS

None known.

OVERDOSE & TREATMENT

No adverse clinical symptoms were observed in chickens and turkeys treated respectively with doses up to 10 and 6 times higher than the therapy dose.

The use of fluoroquinolones during the growth phase combined with a marked and prolonged increase in the intake of drinking water, and hence active ingredient, possibly due to high temperatures, may potentially be associated with damage of the articular cartilage.

WITHDRAWAL PERIOD

Chickens: Meat and offal: 7 days.

Turkeys: Meat and offal: 13 days.

Not authorized for use in birds producing eggs for human consumption.

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

MAXIMUM RESIDUAL LIMIT (MRL)

Substance	Drug Definition of residues in which MRL was set	Food	Maximum Residue Limits (MRLs) in food µg/kg
Enrofloxacin	Sum of enrofloxacin and ciprofloxacin	Muscle	100
		Skin + Fat	100
		Liver	200
		Kidney	300

STORAGE CONDITION

Store below 30°C. Protect from direct sunlight.

SHELF LIFE

2 years.

After 1st opening, reconstitution or dilution, use within 24 hours.

PACKING

1 L

THYE PHARMA SDN. BHD.

(manufacturer & product registration holder)

No.2 Lorong Industri Ringan Permatang

Tinggi 8,

Kawasan Industri Ringan Permatang Tinggi,

14000 Bukit Mertajam,

Pulau Pinang.

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