

ENROFLO 200 (Enrofloxacin 20% w/v oral solution)

ACTIVE INGREDIENT PER ML

Enrofloxacin200mg

Content of preservative : Benzyl alcohol : 10mg

DESCRIPTION:

A yellow color, clear liquid

DOSAGE FORM:

Solution for administration in drinking water.

Clear slightly yellow solution.

PHARMACODYNAMICS:

Action mode

Two basic enzymes in replication have been identified as the main targets of fluoroquinolones and DNA transcription, DNA gyrase and DNA topoisomerase IV. They modulate the topological state of DNA by subsequent separation and bonding reactions. Initially, the two strands of the DNA double helix separate. Subsequently, a distant segment of DNA passes through this cut before the posterior union of the strands. The inhibition is caused by the non-covalent binding of fluoroquinolone molecules to an intermediate state in this state. Sequence of reactions, in which DNA is separated but both chains are covalently held together by enzymes. Replication forks and translation complexes cannot continue beyond complexes fluoroquinolone-DNA-enzyme. Inhibition of DNA and mRNA synthesis triggers rapid death, concentration-dependent pathogenic bacteria.

Antibacterial spectrum:

Enrofloxacin is effective against Gram negative, Gram positive and Mycoplasma spp bacteria. In vitro sensitivity has been demonstrated in strains of (i) Gram negative species such as *Escherichia coli*, *Pasteurella multocida* and *Avibacterium (Haemophilus) paragallinarum* and (ii) *Mycoplasma gallisepticum* and *Mycoplasma synoviae*.

Types and mechanisms of resistance:

Five mechanisms of resistance to fluoroquinolones have been described: (i) point mutation of genes that encode DNA gyrase and / or topoisomerase IV causing alterations of the respective enzymes, (ii) alterations of drug permeability in Gram negative bacteria, (iii) expulsion mechanisms, (iv) mediated resistance by plasmids and (v) gyrase protective proteins. These mechanisms cause less sensitivity of bacteria to fluoroquinolones. The cross-resistance between antimicrobials of the fluoroquinolone class.

PHARMACOKINETICS:

Enrofloxacin is rapidly absorbed in chickens after administration in drinking water, with bioavailability of about 90%.

If dosed continuously using medicated drinking water (multiple dose), concentrations constants from 0.5 mg (turkeys) to 0.8 mg (chickens) enrofloxacin per liter. A high volume of distribution medium (5 l / kg) indicates an extensive diffusion of enrofloxacin to the tissues. Concentrations higher than the plasma concentration in the target tissues of the lung, liver, kidney, intestine and muscle tissue. In chickens the metabolization of enrofloxacin to ciprofloxacin in birds is poor (approximately 5%). The half-life of elimination of enrofloxacin is 6 hours. Plasma protein binding is approximately 25%.

TARGET SPECIES:

Chickens ,turkeys and rabbits

INDICATIONS:

Chickens

Treatment of infections caused by the following enrofloxacin sensitive bacteria:

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

Turkeys

Treatment of infections caused by the following enrofloxacin sensitive bacteria:

Mycoplasma gallisepticum,
Mycoplasma synoviae,
Pasteurella multocida.

Rabbits

Treatment of infections caused by *Pasteurella multocida* and bacterial enteritis caused by *E.coli*.

Enrofloxacin should be used when clinical experience indicates that enrofloxacin is the active substance of choice. When possible, it will be confirmed with sensitivity tests.

RECOMMENDED DOSAGE :

Chickens and turkeys:

10 mg enrofloxacin / kg body weight, equivalent to 0.05 ml of veterinary medicinal product / kg body weight, per day for 3-5 consecutive days.

Treatment for 5 consecutive days in case of mixed infections and in chronic processes. If not observed clinical improvement after 2 - 3 days, treatment should be reconsidered based on a sensitivity test.

Administration in drinking water. Check that the dose to be administered is completely consumed. Medicated water It should be prepared daily, just before starting daily treatment. Medicated water should be the only source of water during treatment. Animals should be weighed as accurately as possible to avoid an underdosing.

Use only the medicated water prepared daily just before starting treatment. Systems Supply should be checked periodically to ensure adequate consumption of the medication. Empty the delivery system and fill it with medicated water before the start of treatment.

The daily amount (ml) of the medicine required is calculated using the following formula:

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

Rabbits:

10 mg enrofloxacin / kg bw, equivalent to 0.05 ml of veterinary medicinal product / kg bw, per day for 5 days in a row. The daily amount (ml) of the medicine required is calculated using the following formula:

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

ROUTE OF ADMINISTRATION:

Oral

CONTRA-INDICATIONS:

Do not use for prophylaxis.

Do not use if resistance or cross-resistance to (fluoro) quinolones has been identified. in the group of animals to be treated.

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

WARNINGS AND PRECAUTIONS

Special warnings for each target species

Treatment of *Mycoplasma spp.* Infections may not eradicate the micro-organism

Special precautions for use

Special precautions for use in animals

The drug should be used with due regard to local and official antimicrobial policies.

Fluoroquinolones should be reserved for the treatment of clinical conditions that have responded poorly or that they will foreseeably respond poorly to other antimicrobial groups.

To the extent possible, the use of fluoroquinolones should always be based on sensitivity analysis.

The use of the drug without following the instructions contained in the technical sheet may increase the prevalence of Fluoroquinolone resistant bacteria and reduce the effectiveness of treatment with other quinolones by a possible cross resistance.

Since enrofloxacin was first authorized for use in poultry, there has been a reduction generalized in the sensitivity of *E. coli* to fluoroquinolones and the appearance of resistant microorganisms.

Specific precautions to be taken by the person administering the veterinary medicinal product to animals

People with known hypersensitivity to fluoro (quinolones) should avoid all contact with the drug.

Wear gloves and handle the veterinary medicine carefully to avoid contact during its incorporation to the drinking water.

Avoid contact with skin and eyes. In case of contact, immediately wash with plenty of water.

If symptoms appear after exposure, such as a rash, consult a doctor and show these warnings. Inflammation of the face, lips or eyes or shortness of breath are more serious signs that require urgent medical attention.

Do not smoke, eat or drink while handling the medicine.

INTERACTIONS WITH OTHER MEDICAMENTS:

In vitro, an antagonistic effect has been demonstrated when fluoroquinolones are combined with other antimicrobials Bacteriostats such as macrolides, tetracyclines, or phenols. The concomitant administration of substances that Containing magnesium or aluminum can reduce the absorption of enrofloxacin.

PREGNANCY AND LACTATION:

Its use is not authorized in laying birds whose eggs are used for human consumption.

Do not use in replacement laying birds in the 14 days prior to the start of lay.

SIDE EFFECTS:

None known.

SYMPTOMS AND TREATMENTS OVERDOSE:

No adverse clinical signs have been observed in chickens and turkeys after dosing up to 10 and 6 times the therapeutic dose, respectively.

The use of fluoroquinolones during the growth phase together with a strong and prolonged increase in the intake of drinking water and consequently of active substance, possibly due to high temperatures, can be associated with articular cartilage injuries.

WITHDRAWAL PERIOD:

Chickens: Meat: 7 days

Turkeys: Meat: 13 days

Rabbits: Meat: 3 days

Its use is not authorized in laying birds whose eggs are used for human consumption.

Do not use in replacement laying birds in the 14 days prior to the start of lay.

STORAGE CONDITIONS:

Storage below 30°C

Protect from light and moisture for veterinary use only .

Keep away from children

Jauhkan dari kanak-kanak

Proposed Shelf Life (as packaged for sale)

2 years

Proposed Shelf Life (after first opening of container)

28 days

Proposed Shelf life (after reconstitution or dilution)

The solution is discarded 24 hours after reconstitution

PACKING:

High-density polyethylene bottle and drum, closed with screw cap with polyethylene seal with disc induction. Formats: 1 l bottle

MANUFACTURED BY:

NAM PHARMA SDN. BHD.

5, Lebuhr Perusahaan Kelebang

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31200 Chemor, Perak

Malaysia

NAME & ADDRESS OF PRODUCT REGISTRATION HOLDER

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