

PBAC NORFLOXACIN 200MG/ML ORAL SOLUTION

FOR ANIMAL USE ONLY

Brand or Product Name :

PBAC NORFLOXACIN 200MG/ML ORAL SOLUTION

Name and Strength of Active Substance(s)

Each ml contains 200mg norfloxacin.

Product Description

A light yellowish solution.

Pharmacodynamics

Norfloxacin is an orally absorbed fluoroquinolone antibacterial with a fluorine at position 6 and a piperazine ring at position 7. These changes have resulted in a marked enhancement (compared with that of the older quinolones) of in vitro antibacterial activity. Antimicrobial activity : Norfloxacin has excellent activity against a wide variety of Gram-negative bacteria, including Enterobacteriaceae, *Actinobacillus pleuropneumoniae*, *Haemophilus somnus*, *Mannheimia (Pasteurella) haemolytica*, *Pseudomonas aeruginosa* and *Pasteurella multocida*. It is also active against *Bordetella bronchiseptica*, *Brucella* spp., *Chlamydia* spp., *Staphylococci* (including penicillinase-producing and methicillin-resistant strains), *Mycoplasma* spp and *Ureaplasma*. Relative to its activity against gram-negative bacteria, norfloxacin is somewhat less active against gram-positive cocci. In general, the staphylococci are more susceptible to the drug than are the streptococci. As with all fluoroquinolones, norfloxacin's activity against anaerobic bacteria is poor. Mechanism of Action : Norfloxacin is a bactericidal agent. It inhibits bacterial DNA gyrase (a type-II topoisomerase), thereby preventing DNA supercoiling and DNA synthesis.

Pharmacokinetics

Norfloxacin is well absorbed after oral administration, highly lipid-soluble and penetrates tissues very rapidly and often reaching tissue concentrations higher than serum levels. The concentration of norfloxacin and its metabolites were found to be highest in bile, followed by intestinal contents, liver, small intestine, kidney and lung.

Indication

For the treatment of respiratory tract infection, urinary tract infection and gastrointestinal tract infections caused by norfloxacin susceptible bacteria such as *E. coli*, *Haemophilus*, *Mycoplasma*, *Pasteurella* and *Salmonella* in poultry and swine.

Recommended Dosage

For oral administration via drinking water.

Poultry: 1 Litre per 1500 - 4000 Litres of drinking water for 3 - 5 days.

Swine: 1 Litre per 1000 - 3000 Litres of drinking water for 3 - 5 days.

Direction of Use

To be administered via animal drinking water.

Contraindications

The drug should not be used for prophylaxis.

Warnings and Precautions

Special precautions for use in animal

Whenever possible, this product should only be used based on susceptibility testing. The product must be used accordance with the instruction prescribed (dosage, duration and indications) to avoid increase prevalence of bacteria resistant and decrease effectiveness of treatment with other quinolones due to potential for cross resistance.

The drug should not be administered to laying hens.

Special precaution for user

Those with known hypersensitivity to (fluro)quinolones should avoid contact with this product. Avoid contact with skin and eyes. Wear impervious gloves when handling the product. Wash 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. If ingest the product accidentally, get medical attention immediately.

Interactions with Other Medicaments

None known.

Statement on usage during pregnancy and lactation

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only accordingly to the benefit/risk assessment by the responsible veterinarian. Not for use in chickens laying eggs for human consumption.

Adverse Effects

None known. If side effects are observed, it is recommended that you consult a veterinarian immediately

Overdose and Treatment

Stop medication and to seek for veterinarian advice if there is sign of overdose.

Withdrawal Period(s)

Swine : 8 days. Poultry : 12 days.

Shelf-life

2 years from date of manufactured. Opened bottle is to be discarded after 24 hours. Medicated water must be prepared fresh daily. Any unused medicated water is to be discarded after 24 hours.

Allowable Maximum Residual Limit

Muscle, fat, liver, kidney, edible offal: Poultry and Swine = 20 µg/kg [Source : The Japan Food Chemical Research Foundation]

Storage Conditions

Store airtight at room temperature (below 30°C). Keep out of reach of children.

Disposal of containers

Traces of medicated liquid left in an opened bottle can be rinsed out with clean animal drinking water and use in animal treatment. Cleaned empty bottle can be safely disposed in trash according to local government regulations.

Dosage Forms and packaging available

Available in 1 litre per bottle, pack in 12 bottles or 20 bottles per carton.

Name and Address of manufacturer

Life Biopharma Sdn. Bhd. (546163-D)

No. 250-251, Jalan Industri Galla 13, Kawasan Perindustrian Galla, 70200 Seremban, Negeri Sembilan, Malaysia.

Date of Revision of Package Insert

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