

Batch:
Expiry:

ANTIBACTERIAL INJECTION

Baytril® 50



01499977

**PRESCRIPTION ANIMAL REMEDY
KEEP OUT OF REACH OF CHILDREN
FOR ANIMAL TREATMENT ONLY**



Baytril® 50

ANTIBACTERIAL INJECTION

Active Constituent:

50 mg/mL ENROFLOXACIN



For the treatment of diseases
caused by susceptible bacterial
pathogens in dogs and cats

50 mL

Baytril® 50

READ THE ENCLOSED LEAFLET BEFORE
USING THIS PRODUCT.

DIRECTIONS FOR USE.

Restraints

DO NOT USE in food producing species
of animals.

FOR USE ONLY in companion animals
where culture and sensitivity testing indicate
no suitable alternative.

Contraindications

Not for use in dogs less than one year of
age, or cats less than 12 weeks of age (see
leaflet).

The dose of Baytril is 5 mg/kg per day by
subcutaneous injection equivalent to: **1 mL
Baytril 50 Injection per 10 kg bodyweight.**
Baytril Tablets or Baytril Oral Solution may be
used for follow-up treatment after an initial
dose of Baytril Injection.

First Aid

If poisoning occurs contact a doctor or
Poisons Information Centre.
Phone Australia 131126.

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45 x 45 x 85

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Bayer Australia Ltd
ACN 000 138 714
875 Pacific Highway
Pymble NSW 2073

Disposal: Dispose of empty packaging by
wrapping with paper and putting in garbage.
Store below 30°C (Room Temperature).

APVMA 46028/1/0705

For Batch and Expiry see top of pack.

BAYTRIL® is a trademark of
Bayer AG, Leverkusen, Germany

**CUSTOMER
INFORMATION LINE**

☎ 1 800 678 368

TOLL FREE

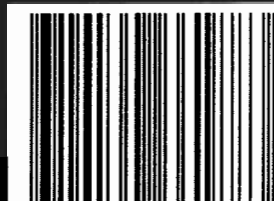
from anywhere in Australia

9.00 am to 4.00 pm

(Eastern Time) Monday to Friday



Bayer HealthCare



9 310160 661883

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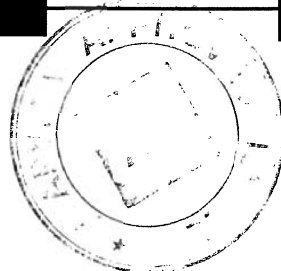
01499969



Bayer HealthCare

Batch:

Expiry:



**PRESCRIPTION ANIMAL REMEDY
KEEP OUT OF REACH OF CHILDREN
FOR ANIMAL TREATMENT ONLY**

Magnification = X0.92

Baytril® 50
flavour
ANTIBACTERIAL TABLETS
50 mg ENROFLOXACIN



Baytril® 50
ANTIBACTERIAL INJECTION
50mg/mL ENROFLOXACIN

Baytril® 150
flavour
ANTIBACTERIAL TABLETS
150 mg ENROFLOXACIN



Baytril® 25
ANTIBACTERIAL ORAL SOLUTION
25mg/mL ENROFLOXACIN

DESCRIPTION:

Enrofloxacin is a synthetic drug from the class of the quinolone carboxylic acid derivatives, also known as fluoroquinolones. It has antibacterial activity against a broad spectrum of gram negative and gram positive bacteria, including Mycoplasma. (See Table 1). It is rapidly absorbed from the digestive tract, penetrating into all measured body tissues and fluids (See Table 2). Enrofloxacin has the chemical name 1-cyclopropyl-7-(4-ethyl-1-piperazinyl)-6-fluoro-1, 4-dihydro-4-oxo-3-quinolinecarboxylic acid. It is presented as tablets, an injection, and as an oral solution.

MICROBIOLOGY:

Enrofloxacin exerts bactericidal activity by interaction with the A subunit of DNA gyrase in the target bacteria. The DNA gyrase is a topoisomerase which controls bacterial replication, i.e., it catalyses supercoiling by rewinding and rejoining of chromosomal DNA strands. The fluoroquinolones also possess activity against bacteria in the stationary phase by an alteration of the permeability of the outer membrane phospholipid layer of the cell wall. These mechanisms of action explain the rapid loss of viability of susceptible bacteria. With enrofloxacin, inhibitory and bactericidal concentrations are closely correlated. They are identical or differ in many cases within one or two dilution steps at maximum. Enrofloxacin possesses antimicrobial activity at low concentration against most gram negative bacteria, many gram positive bacteria and against mycoplasmas. Enrofloxacin is therefore active against the micro-organisms that are primarily or secondarily involved in many of the infectious diseases which occur in small animals.

TABLE 1. Minimum Inhibitory Concentrations for enrofloxacin against pathogens isolated from dogs and cats.

| Organism | No of Strains | MIC µg/mL |
|---|---------------|----------------|
| Gram negative organisms | | |
| <i>E. coli</i> | 180 | 0.01 - 0.5 |
| <i>Salmonella</i> spp | 115 | 0.003 - 0.5 |
| <i>Klebsiella</i> spp | 48 | <0.03 - 0.5 |
| <i>Proteus</i> spp | 55 | 0.03 - 0.5 |
| <i>Pseudomonas aeruginosa</i> | 43 | 0.156 - 5.0 |
| <i>Brucella canis</i> | 3 | 0.1 - 0.25 |
| <i>Bordetella bronchiseptica</i> | 31 | 0.1 - 4.0 |
| Gram positive organisms | | |
| <i>Staph. aureus</i> | 135 | 0.03 - 1.0 |
| <i>Staph. intermedius</i> | 2 | 0.039 - 0.3125 |
| <i>Streptococcus</i> spp. | 62 | 0.06 - 4.0 |
| <i>Arcanobacterium (Corynebacterium) pyogenes</i> | 29 | 0.06 - 4.0 |
| Mycoplasmas | | |
| <i>Mycoplasma</i> spp | 92 | 0.01 - 1.0 |

DISTRIBUTION AND METABOLISM

Distribution in the Body: Enrofloxacin penetrates into all canine and feline tissues and body fluids. Concentrations of drug equal to or greater than the MIC for many pathogens (See Table 1) are reached in most tissues within two hours of dosing and are maintained for eight hours after dosing. Particularly high levels of enrofloxacin are found in urine. A summary of the body fluid/tissue drug levels at 1 and 8 hours after dosing is given in Table 2 for a 5 mg/kg oral dose in dogs and cats.

TABLE 2. Enrofloxacin body fluid and tissue levels at 1 and 8 hours after oral treatment in dogs and cats at 5 mg/kg.

| TISSUE | DOG | | CAT | |
|-------------|---------------------------------------|---------|--------|---------|
| | Average Concentration µg/mL or µg at: | | | |
| | 1 hour | 8 hours | 1 hour | 8 hours |
| Serum | 0.9 | 0.3 | 2.2 | 1.3 |
| Lung | 2.5 | 0.7 | 4.5 | 2.1 |
| Liver | 5.8 | 1.1 | 6.5 | 2.6 |
| Kidney | 3.5 | 1.0 | 5.4 | 2.5 |
| Spleen | 2.8 | 0.9 | 3.0 | 1.6 |
| Heart | 3.1 | 1.0 | 5.0 | 2.2 |
| Adrenal | 2.1 | 0.6 | - | - |
| Muscle | 2.3 | 1.2 | 2.8 | 2.3 |
| Skin | 0.7 | 0.7 | 1.9 | 1.1 |
| Fat | 1.4 | 0.4 | 1.3 | 0.4 |
| Rib bone | 0.7 | 0.9 | 2.2 | 2.0 |
| Brain | 0.4 | 0.1 | 1.6 | 0.7 |
| Eye - humor | 0.09 | 0.1 | 0.5 | 1.2 |
| Eye - iris | 0.2 | 0.3 | - | - |
| Uterus | 0.2 | 0.8 | 2.2 | 1.1 |
| Ovary | 0.3 | 0.9 | 2.4 | 1.2 |
| Testes | 1.9 | - | - | - |
| Bile | 30.0 | 57.0 | 39.0 | - |
| Urine | 25.0 | 49.0 | 30.1 | - |
| CSF | 0.9 | 0.1 | 1.0 | 0.7 |

- = not tested

Pharmacokinetics:

Following an oral dose in dogs, enrofloxacin reaches its peak serum level in one hour. The elimination half-life is greater than three hours at 2.5 mg/kg. Approximately 80% of the orally administered dose enters the systemic circulation unchanged. The eliminating organs, based on the drug's body clearance time, can readily remove the drug with no indication that the eliminating mechanisms are saturated. The primary route of excretion is via the urine. Table 3 below shows typical blood levels for dogs and cats after oral and parenteral administration at the recommended dose.

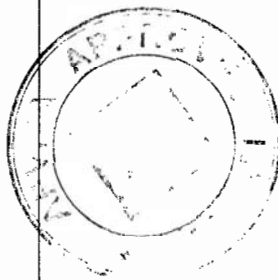
TABLE 3. Enrofloxacin serum levels at various times after administration at 5 mg/kg in dogs and cats.

| | ROUTE | MEAN SERUM LEVEL µg/mL at hours | | | | | | | |
|-----|-------|---------------------------------|------|------|------|------|------|------|-------|
| | | 0.5 | 1 | 2 | 4 | 6 | 8 | 12 | 24 |
| DOG | Oral | 0.6 | 1.25 | 1.19 | 0.74 | 0.46 | 0.36 | 0.14 | <0.04 |
| | SC | 1.0 | 1.1 | 1.0 | 0.7 | 0.4 | - | - | nd |
| CAT | Oral | - | 1.51 | 1.9 | 1.72 | 1.07 | - | 0.41 | 0.04 |
| | SC | - | 1.19 | 1.31 | 1.09 | 0.79 | - | 0.22 | 0.02 |

Levels are a mean of 4-8 dogs per group and 3 cats per group
- = not tested nd = not detected

INDICATIONS:

- Primary indications for use in the dog and cat are:
- * Urinary tract infections including infections with *E. coli*, *Proteus* spp., *Klebsiella* spp., *Pseudomonas aeruginosa*, *Staph* spp., and Group D *Streptococcus*.
 - * Respiratory infections, including infections with *E. coli*, *Streptococcus* spp., *Pasteurella* spp., *Klebsiella* spp., *Pseudomonas* spp., *Bordetella bronchiseptica*, *Staphylococcus* spp.
 - * Deep pyodermas caused by *Staph. intermedius* including those infected with secondary invaders.
 - * Wounds, abscesses and discharging sinuses.
 - * Baytril is especially useful in cats for treating serious antibiotic resistant infections of the respiratory tract or genito-urinary system, particularly chronic urinary tract infections. In cats it is also useful for deep pyodermas, osteomyelitis and Gram negative septicaemias.
- Baytril may also be used in exotic animals (small mammals, reptiles and avian species) for the treatment of bacterial infections of the alimentary and respiratory tracts where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice.



DIRECTIONS FOR USE:

Restraints

DO NOT USE in food producing species of animals.

FOR USE ONLY in companion animals where culture and sensitivity testing indicate no suitable alternative.

Contraindications:

Dogs Based on the studies discussed below under the section on Animal Safety, the use of enrofloxacin is contraindicated in dogs during the rapid growth phase. Baytril should not be used in dogs under one (1) year of age. Giant breeds may be in the rapid growth phase for up to 18 months. Care should be used in treating individuals of these breeds with Baytril when they are younger than 18 months.

Cats Baytril should not be used in cats less than 12 weeks of age. The safe use of enrofloxacin in breeding female cats has not been established.

Precaution

Although rare, it is prudent to consider that any fluoroquinolone may have the potential to induce retinal degeneration in cats, especially when used above label dose rates or in animals that may be elderly or suffering from renal or hepatic disease.

DOSAGE

Dogs & Cats

The optimum dose of Baytril in dogs and cats is **5 mg/kg of body-weight** administered once daily.

Oral and injectable routes are bioequivalent.

Baytril Injection should be administered subcutaneously and normal sterile precautions should be taken.

In simple infections, Baytril should be given for 2-3 days beyond the cessation of clinical signs. Baytril Injection may be used as the initial dose. If no improvement is seen within five days, the diagnosis should be re-evaluated and a different course of therapy considered. In deep or complex infections, eg pyoderma, discharging sinuses, extended courses may be required and progress should be regularly reviewed.

Exotic Animals

| Species | Dosage | Route | Dose Frequency | Treatment Duration |
|---------------|----------|-----------|----------------------|--------------------|
| Small mammals | 5 mg/kg | s.c./oral | Twice daily | 7 days |
| Reptiles | 5 mg/kg | i.m./oral | 24-48 hour intervals | 6 days |
| Avian spp | 10 mg/kg | i.m./oral | Twice daily | 7 days |

Treatment may be initiated with Baytril Injection and should, if possible, be maintained with Baytril Oral Solution or Tablets as appropriate. The use of tuberculin or insulin syringes and/or dilution of Baytril Injection with sterile water for injection should be considered for administration of very small volumes.

Dose Selection

Select an appropriate dose from one of the following formulations

| Presentation | Dosage to achieve 5 mg/kg (except avians) |
|--|---|
| Baytril 50 flavour Antibacterial Tablets (50 mg/tab) | 1 tablet per 10 kg bodyweight |
| Baytril 150 flavour Antibacterial Tablets (150 mg/tab) | 1 tablet per 30 kg bodyweight |
| Baytril 25 Antibacterial Oral Solution (25 mg/mL) | 1 mL per 5 kg bodyweight |
| Baytril 50 Antibacterial Injection (50 mg/mL) | 1 mL per 10 kg bodyweight |

In all species vary the injection site when multiple injections are given.

ADVERSE REACTIONS:

Dogs Two of the 270 (0.7%) dogs treated orally with Baytril in clinical field studies exhibited side effects, which were apparently drug related. These two cases of vomiting were self-limiting. No drug related side effects were reported in 122 clinical cases treated with Baytril Injectable Solutions followed by Baytril Tablets.

Cats No drug related side effects were reported in 124 cats treated with Baytril Tablets in clinical field studies.

Exotic Species Muscle bruising in reptiles and birds after injection has been reported occasionally.

DRUG INTERACTIONS:

Dogs Enrofloxacin has been administered to dogs concurrently with a wide variety of other products including anthelmintics (praziquantel, febantel, sodium disphenol), insecticides (fenitrothion, pyrethrins), heartworm preventatives (diethylcarbamazine), and other antibiotics (ampicillin, gentamicin sulfate, penicillin, dihydrostreptomycin). No incompatibilities with other drugs are known at this time except that fluoroquinolones may interfere with the metabolism of theophylline and related drugs (e.g. aminophylline) so the dosage of theophylline may need to be reduced.

Cats Enrofloxacin was administered concurrently with anthelmintics (praziquantel, febantel), a carbamate insecticide (propranolol), and another antibacterial (ampicillin).

No incompatibilities with other drugs are known at this time.

ANIMAL SAFETY:

Dogs

1. Adults:

Dogs receiving enrofloxacin at 12.5 mg/kg (2.5X) twice daily or 25 mg/kg (5X) daily for 28 and 30 days respectively showed no abnormalities. Dogs dosed at 52 mg/kg (10X) for 13 weeks showed only isolated incidences of vomiting and inappetence. Dosages of 125 mg/kg (25X) are toxic and may be lethal if given repeatedly.

2. Growing Dogs:

Oral treatment of 15 to 28 week old growing puppies with daily dosages of 25 mg/kg has induced abnormal carriage of the carpal joint and weakness in the hindquarters. However significant improvement of clinical signs is observed following drug withdrawal. Microscopic studies have identified lesions of the articular cartilage following 30 day treatments at either 5, 15 or 25 mg/kg in this age group.

3. General Safety:

Tests indicated no effect on circulating microfilariae or adult heartworms (*Dirofilaria immitis*). Baytril has no effect on cholinesterase levels.

4. Reproduction:

No abnormalities in reproductive parameters were observed when male dogs received 10 consecutive daily treatments of 15 mg/kg/day at 3 intervals (90, 45 and 14 days) prior to breeding. Nor when female dogs received 10 consecutive daily treatments of 15 mg/kg/day at 4 intervals: between 30 and 0 days prior to breeding, early pregnancy (between 10th and 30th days), late pregnancy (between 40th and 60th days), and during lactation (the first 28 days).

Cats

1. Adults:

Cats receiving 50 mg/kg (10X) of enrofloxacin for 6 days showed clinical signs of vomiting, inappetence, in-coordination and convulsions, but returned to normal on withdrawal of the drug. Dosages of 125 mg/kg (25X) for 5 consecutive days induced vomiting, depression, inco-ordination and lead to death.

2. Growing Cats:

Cats in age ranges of 3 to 4 months and 7 to 10 months received daily treatments of 25 mg/kg (5X) for 30 consecutive days with no adverse effects. Occasional vomiting was seen in 7 to 10 month old cats during 30 days of consecutive dosing at 5, 15, or 25 mg/kg. Growing kittens 5 to 7 months old showed articular cartilage lesions when dosed with 25 mg/kg (5X) for 30 days but no lesions were seen at 15 mg/kg (3X) for 30 days.

Exotic Species:

In the absence of data on its use in some exotic species, caution should be used when prescribing during pregnancy or lactation in small mammals and a careful risk/benefit assessment made.

FIRST AID

If poisoning occurs contact a doctor or Poisons Information Centre. Phone Australia 131126.

MATERIAL SAFETY DATA SHEET

Additional information is listed in the Material Safety Data Sheet.

DISPOSAL

Dispose of used packaging by wrapping in paper and placing in garbage.

STORAGE

Store below 30°C (Room Temperature)

PRESENTATION

Baytril 50 flavour Antibacterial Tablets APVMA 58010/0705 (50 mg per tab)

Baytril 150 flavour Antibacterial Tablets APVMA 58011/0705 (150 mg per tab)

Baytril tablets are supplied in foils of 10 tablets (100 tablets per carton)

Baytril 50 Antibacterial Injection APVMA 46028/0705 (50 mg per mL) - 50 mL

Baytril 25 Antibacterial Oral Solution APVMA 46027/0705 (25 mg per mL) - 100 mL

Bayer Australia Ltd

ACN 000 138 714, 875 Pacific Highway, Pymble NSW 2073

CUSTOMER INFORMATION LINE
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TOLL FREE
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Bayer HealthCare