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## FREEDOM OF INFORMATION SUMMARY

### I. General Information:

**NADA No.:** 140-441

**Sponsor:** Bayer Corporation,  
Agriculture Division  
Animal Health  
P.O. Box 390  
Shawnee Mission, Kansas 66201

**Generic Name:** Enrofloxacin

**Trade Name:** Baytril® Taste Tabs™ Antibacterial Tablets

**Marketing Status:** Rx

**Effect of Supplement:** This supplement amends the NADA to add a 136 mg tablet and the associated label changes. The currently approved tablet sizes are 22.7 and 68 mg.

### II. Indications for Use:

The indications for use remain the same as currently approved. Baytril Taste Tabs Antibacterial Tablets are indicated for the management of diseases in dogs and cats associated with bacteria susceptible to enrofloxacin.

### III. Dosage Form(s), Route(s) of Administration, and Recommended Dosage(s):

Administer orally at a rate to provide 5 – 20 mg/kg (2.27 – 9.07 mg/lb) of body weight, either as a single daily dose or divided into two (2) equal daily doses administered at twelve (12) hour intervals. Selection of a dose within this range should be based on clinical experience, the severity of disease, and the susceptibility of the pathogen. The dose should be continued for at least 2 – 3 days beyond cessation of clinical signs, to a maximum of 30 days. Animals which receive doses at the upper-end of the dose range should be carefully monitored for clinical signs that may include inappetence, depression, or vomiting.

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**IV. Safety and Effectiveness:**

The approval of the 136 mg tablet does not require safety or effectiveness data as the dosage remains the same as currently approved. The approval is based on the manufacturing information on containers/closures, labeling, dissolution, and the stability of the 136 mg tablet.

**V. Human Safety:**

Human Food Safety

Data on human safety, pertaining to consumption of drug residues in food, were not required for approval of this NADA. The formulation is labeled for use in dogs and cats only.

User Safety

The labeling contains adequate directions for use and thus poses no human safety hazard. The labeling contains adequate "WARNING" and "CAUTION" statements.

**VI. Agency Conclusions:**

The data submitted in support of this NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act (FFDCA) and Part 514 of the implementing regulations (Title 21), and demonstrate that BAYTRIL<sup>®</sup> Taste Tabs<sup>™</sup> 136 mg Antibacterial Tablets are safe and effective when used according to the approved conditions of use.

The drug is restricted to use by or on the order of a licensed veterinarian because professional expertise and proper diagnosis is required for safe use and treatment success.

Under section 512(c)(2)(F)(iii) of the FFDCA, this approval for non food producing animals does not qualify for marketing exclusivity because the supplemental application does not contain substantial evidence of the effectiveness of the drug involved, or any studies of animal safety required for the approval and conducted or sponsored by the applicant.

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**VII. Labeling (attached):**

- A. Baytril® (enrofloxacin) Taste Tabs™ 136 mg Antibacterial Tablets, 50 tablet bottle label
- B. Baytril® (enrofloxacin) Taste Tabs™ 136 mg Antibacterial Tablets, 200 tablet bottle label
- C. Package Insert

**Baytril®**  
(enrofloxacin)

Taste Tabs™ 136 mg Antibacterial Tablets

**136**

**For The Treatment Of Susceptible Bacterial  
Pathogens In Dogs And Cats**

Caution: Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.

50 Tablets

**Bayer** 

Bayer Corporation, Agriculture Division, Animal Health  
Shawnee Mission, Kansas 66201 U.S.A.  
NADA 140-441, Approved by FDA

**DOSAGE:** Administer orally at a rate to provide 5-20 mg/kg (2.27 to 9.07 mg/lb) of body weight, either as a single daily dose or divided into two (2) equal daily doses administered at twelve (12) hour intervals. Selection of a dose within this range should be based on clinical experience, the severity of disease, and the susceptibility of the pathogen. This dose should be continued for at least 2-3 days beyond cessation of clinical signs, to a maximum of 30 days. Animals which receive doses at the upper-end of the dose range should be carefully monitored for clinical signs that may include inappetence, depression, or vomiting.

**CONTRAINDICATIONS:** The use of enrofloxacin is contraindicated in small and medium breeds of dogs during the rapid growth phase (between 2 and 8 months of age). The safe use of enrofloxacin has not been established in large and giant breeds during the rapid growth phase. Consult package insert for details.

**WARNING:** For use in Animals Only. Keep Out of Reach of Children.

Read package insert carefully for complete details.  
0417 71004170, R.0

Lot No.:  
Exp. Date:

EDP #: 71004170, R.0  
Colors: PMS 368 Green Process Cyan  
PMS 247 Black  
PMS 332 Red (Use Line)  
Size: 2 1/4" x 6 1/4"  
UPC: None

Trap: .008"  
Corner Radius: .125"  
Screen: 150  
Printer: CCL Label

30349

# Baytril® (enrofloxacin)

Taste Tabs™ 136 mg Antibacterial Tablets

# 136

## For The Treatment Of Susceptible Bacterial Pathogens In Dogs And Cats

Each tablet contains 136 mg enrofloxacin.  
Caution: Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.

200 Tablets



Bayer Corporation, Agriculture Division, Animal Health  
Shawnee Mission, Kansas 66201 U.S.A.  
NADA 140-441, Approved by FDA

**DOSAGE:** Administer orally at a rate to provide 5-20 mg/kg (2.27 to 9.07 mg/lb) of body weight, either as a single daily dose or divided into two (2) equal daily doses administered at twelve (12) hour intervals. Selection of a dose within this range should be based on clinical experience, the severity of disease, and the susceptibility of the pathogen. This dose should be continued for at least 2-3 days beyond cessation of clinical signs, to a maximum of 30 days. Animals which receive doses at the upper-end of the dose range should be carefully monitored for clinical signs that may include inappetence, depression, or vomiting.

**CONTRAINDICATIONS:** The use of enrofloxacin is contraindicated in small and medium breeds of dogs during the rapid growth phase (between 2 and 8 months of age). The safe use of enrofloxacin has not been established in large and giant breeds during the rapid growth phase. Consult package insert for details.

**WARNING: For Use in Animals Only. Keep Out of Reach of Children.**

Read package insert carefully for complete details.

0391

71003910, R.0

Lot No.:  
Exp. Date:

EDP #: 71003910, R.0  
Colors: PMS 366 Green Process Cyan  
PMS 247 Black  
PMS 032 Red (Die Line)  
Size: 3" x 6 3/4"  
UPC: None

Trap: .008"  
Corner Radius: .125"  
Screen: 150  
Printer: CCL Label

# Baytril® (enrofloxacin)

Taste Tabs™ 136 mg Antibacterial Tablets  
and Injectable Solution

### CAUTION:

Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.

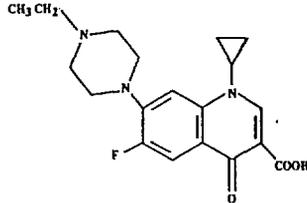
### DESCRIPTION:

Enrofloxacin is a synthetic chemotherapeutic agent from the class of the quinolone carboxylic acid derivatives. It has antibacterial activity against a broad spectrum of Gram negative and Gram positive bacteria (See Tables I and II). It is rapidly absorbed from the digestive tract, penetrating into all measured body tissues and fluids (See Table III).

Tablets are available in three sizes (22.7, 68.0 and 136.0 mg enrofloxacin). Each mL of injectable solution contains: enrofloxacin 22.7 mg, n-butylalcohol 30 mg, potassium hydroxide for pH adjustment and water for injection, q.s.

### CHEMICAL NOMENCLATURE AND STRUCTURAL FORMULA:

1-cyclopropyl-7-(4-ethyl-1-piperazinyl)-6-fluoro-4-oxo-3-quinolincarboxylic acid.



### ACTIONS:

**Microbiology:** Quinolone carboxylic acid derivatives are classified as DNA gyrase inhibitors. The mechanism of action of these compounds is very complex and not yet fully understood. The site of action is bacterial gyrase, a synthesis promoting enzyme. The effect on *Escherichia coli* is the inhibition of DNA synthesis through prevention of DNA supercoiling. Among other things, such compounds lead to the cessation of cell respiration and division. They may also interrupt bacterial membrane integrity.

Enrofloxacin is bactericidal, with activity against both Gram negative and Gram positive bacteria. The minimum inhibitory concentrations (MICs) were determined for a series of 39 isolates representing 9 genera of bacteria from natural infections in dogs and cats, selected principally because of resistance to one or more of the following antibiotics: ampicillin, cephalothin, colistin, chloramphenicol, erythromycin, gentamicin, kanamycin, penicillin, streptomycin, tetracycline, triple sulfas and sulfatrimethoprim. The MIC values for enrofloxacin against these isolates are presented in Table I. Most strains of these organisms were found to be susceptible to enrofloxacin *in vitro* but the clinical significance has not been determined for some of the isolates.

The susceptibility of organisms to enrofloxacin should be determined using enrofloxacin 5 mcg disks. Specimens for susceptibility testing should be collected prior to the initiation of enrofloxacin therapy.

TABLE I - MIC Values for Enrofloxacin Against Canine and Feline Pathogens (Diagnostic laboratory Isolates, 1984)

Organisms	Isolates	MIC Range (mcg/mL)
<i>Bacteroides</i> spp.	2	2
<i>Bordetella bronchiseptica</i>	3	0.125-0.5
<i>Brucella canis</i>	2	0.125-0.25
<i>Clostridium perfringens</i>	1	0.5
<i>Escherichia coli</i>	5*	≤0.016-0.031
<i>Klebsiella</i> spp.	11*	0.031-0.5
<i>Proteus mirabilis</i>	6	0.062-0.125
<i>Pseudomonas aeruginosa</i>	4	0.5-8
<i>Staphylococcus</i> spp.	5	0.125

\* Includes feline isolates.

The inhibitory activity on 120 isolates of seven canine urinary pathogens was also investigated and is listed in Table II.

TABLE II - MIC Values for Enrofloxacin Against Canine Urinary Pathogens (Diagnostic laboratory Isolates, 1985)

Organisms	Isolates	MIC Range (mcg/mL)
<i>E. coli</i>	30	0.06-2.0
<i>P. mirabilis</i>	20	0.125-2.0
<i>K. pneumoniae</i>	20	0.06-0.5
<i>P. aeruginosa</i>	10	1.0-8.0
<i>Enterobacter</i> spp.	10	0.06-1.0
<i>Staph. (coag. +)</i>	20	0.125-0.5
<i>Strep. (alpha hemol.)</i>	10	0.5-8.0

**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 Tables I, II and III) are reached in most tissues by two hours after dosing at 2.5 mg/kg and are maintained for 8-12 hours after dosing. Particularly high levels of enrofloxacin are found in urine. A summary of the body fluid/tissue drug levels at 2 to 12 hours after dosing at 2.5 mg/kg is given in Table III.

Single Oral Dose = 2.5 mg/kg (1.13 mg/lb)

Body Fluids (mcg/mL)	Post-treatment Enrofloxacin Levels			
	Canine (n = 2)		Feline (n = 4)	
	2 Hr.	8 Hr.	2 Hr.	12 Hr.
Bile	-	-	2.13	1.97
Cerebrospinal Fluid	-	-	0.37	0.10
Urine	43.05	55.35	12.81	26.41
Eye Fluids	0.53	0.66	0.45	0.65
Whole Blood	1.01	0.36	-	-
Plasma	0.67	0.33	-	-
Serum	-	-	0.48	0.18
Tissues (mcg/g)				
Hematopoietic System				
Liver	3.02	1.36	1.84	0.37
Spleen	1.45	0.85	1.33	0.52
Bone Marrow	2.10	1.22	1.68	0.64
Lymph Node	1.32	0.91	0.49	0.21
Urogenital System				
Kidney	1.87	0.99	1.43	0.37
Bladder Wall	1.36	0.98	1.16	0.55
Testes	1.36	1.10	1.01	0.28
Prostate	1.36	2.20	1.88	0.55
Ovaries	-	-	0.78	0.56
Uterine Wall	1.59	0.29	0.81	1.05
Gastrointestinal and Cardiopulmonary Systems				
Lung	1.34	0.82	0.91	0.33
Heart	1.88	0.78	0.84	0.32
Stomach	3.24	2.16	3.26	0.27
Small Intestine	2.10	1.11	2.72	0.40
Large Intestine	-	-	0.94	1.10
Other				
Fat	0.52	0.40	0.24	0.11
Skin	0.66	0.48	0.46	0.17
Muscle	1.62	0.77	0.53	0.29
Brain	0.25	0.24	0.22	0.12
Mammary Gland	0.45	0.21	0.36	0.30
Feces	1.65	9.97	0.37	4.18

### Pharmacokinetics:

In dogs, the absorption and elimination characteristics of the oral formulation are linear (plasma concentrations increase proportionally with dose) when enrofloxacin is administered at up to 11.5 mg/kg, twice daily. 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. The absorption and elimination characteristics beyond this point are unknown. In cats, no oral absorption information is available at other than 2.5 mg/kg, administered orally as a single dose. Saturable absorption and/or elimination processes may occur at greater doses. When saturation of the absorption process occurs, the plasma concentration of the active moiety will be less than predicted, based on the concept of dose proportionality.

Following an oral dose in dogs of 2.5 mg/kg (1.13 mg/lb) enrofloxacin reached 50% of its maximum serum concentration in 15 minutes and peak serum level was reached in one hour. The elimination half-life in dogs is approximately 2½-3 hours at that dose, while in cats it is greater than 4 hours. In a study comparing dogs and cats, the peak concentration and the time to peak concentration were not different. A graph indicating the mean serum levels following a dose of 2.5 mg/kg (1.13 mg/lb) in dogs (oral and intramuscular) and cats (oral) is shown in Figure 1.

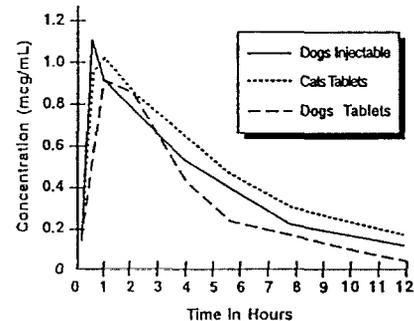


Figure 1 - Serum Concentrations of Enrofloxacin Following a Single Oral or Intramuscular Dose at 2.5 mg/kg in Dogs and a Single Oral Dose at 2.5 mg/kg in Cats.

The lower limit of the dose range was based on efficacy studies in dogs and cats where enrofloxacin was administered at 2.5 mg/kg twice daily. Target animal safety and toxicology studies were used to establish the upper limit of the dose range and treatment duration.

### Breakpoint:

Based on pharmacokinetic studies of enrofloxacin in dogs and cats after a single oral administration of 2.5 mg enrofloxacin/kg BW (i.e. half of the lowest-end single daily dose range) and the data listed in Tables I and II, the following breakpoints are recommended for canine and feline isolates.

Zone Diameter (mm)	MIC (µg/ml)	Interpretation
≥ 21	≤ 0.5	Susceptible (S)
18 - 20	1	Intermediate (I)
≤ 17	≥ 2	Resistant (R)

A report of "Susceptible" indicates that the pathogen is likely to be inhibited by generally achievable plasma levels. A report of "Intermediate" is a technical buffer and isolates falling into this category should be retested. Alternatively the organism may be successfully treated if the infection is in a body site where drug is physiologically concentrated. A report of "Resistant" indicates that the achievable drug concentrations are unlikely to be inhibitory and other therapy should be selected.

Standardized procedures require the use of laboratory control organisms for both standardized disk diffusion assays and standardized dilution assays. The 5 µg enrofloxacin disk should give the following zone diameters and enrofloxacin powder should provide the following MIC values for reference strains.

QC strain	MIC (µg/ml)	Zone Diameter (mm)
<i>E. coli</i> ATCC 25922	0.008 - 0.03	32 - 40
<i>P. aeruginosa</i> ATCC 27853	1 - 4	15 - 19
<i>S. aureus</i> ATCC 25923	0.03 - 0.12	27-31
<i>S. aureus</i> ATCC 29213		

#### INDICATIONS:

Dogs & Cats: Baytril® (brand of enrofloxacin) Taste Tabs™ Antibacterial Tablets and Injectable Solution are indicated for the management of diseases in dogs and cats associated with bacteria susceptible to enrofloxacin.

#### EFFICACY CONFIRMATION:

Dogs: Clinical efficacy was established in dermal infections (wounds and abscesses) associated with susceptible strains of *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, and *Staphylococcus intermedius*; respiratory infections (pneumonia, tonsillitis, rhinitis) associated with susceptible strains of *Escherichia coli* and *Staphylococcus aureus*; and urinary cystitis associated with susceptible strains of *Escherichia coli*, *Proteus mirabilis*, and *Staphylococcus aureus*.

Palatability: Free choice palatability in dogs was confirmed in a study in which 350 individual dosings resulted in a voluntary ingestion rate of 73%.

Cats: Clinical efficacy was established in dermal infections (wounds and abscesses) associated with susceptible strains of *Pasturella multocida*, *Staphylococcus aureus*, and *Staphylococcus epidermidis*.

#### CONTRAINDICATIONS:

Enrofloxacin is contraindicated in dogs and cats known to be hypersensitive to quinolones. Dogs: Based on the studies discussed under the section on Animal Toxicology, the use of enrofloxacin is contraindicated in small and medium breeds of dogs during the rapid growth phase (between 2 and 8 months of age). The safe use of enrofloxacin has not been established in large and giant breeds during the rapid growth phase. Large breeds may be in this phase for up to one year of age and the giant breeds for up to 18 months. In clinical field trials utilizing a daily oral dose of 5.0 mg/kg, there were no reports of lameness or joint problems in any breed. However, controlled studies with histological examination of the articular cartilage have not been conducted in the large or giant breeds.

#### ADVERSE REACTIONS:

Dogs: Two of the 270 (0.7%) dogs treated with Baytril® (brand of enrofloxacin) Tablets at 5.0 mg/kg per day in the 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® (enrofloxacin) Injectable Solution followed by Baytril Tablets at 5.0 mg/kg per day.

Cats: No drug-related side effects were reported in 124 cats treated with Baytril® (Brand of Enrofloxacin) Tablets at 5.0 mg/kg per day for 10 days, in clinical field studies.

#### ANIMAL TOXICOLOGY:

Dogs: Adult dogs receiving enrofloxacin orally at a daily dosage rate of 52 mg/kg for 13 weeks had only isolated incidences of vomiting and inappetence. Adult dogs receiving the tablet formulation for 30 consecutive days at a daily treatment of 25 mg/kg did not exhibit significant clinical signs nor were there effects upon the clinical chemistry, hematological or histological parameters. Daily doses of 125 mg/kg for up to 11 days induced vomiting, inappetence, depression, difficult locomotion and death while adult dogs receiving 50 mg/kg/day for 14 days had clinical signs of vomiting and inappetence.

Adult dogs dosed intramuscularly for three treatments at 12.5 mg/kg, followed by 57 oral treatments at 12.5 mg/kg all at 12 hour intervals, did not exhibit either significant clinical signs or effects upon the clinical chemistry, hematological or histological parameters.

Oral treatment of 15 to 28 week old growing puppies with daily dosage rates of 25 mg/kg has induced abnormal carriage of the carpal joint and weakness in the hindquarters. 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. Clinical signs of difficult ambulation or associated cartilage lesions have not been observed in 29 to 34 week old puppies following daily treatments of 25 mg/kg for 30 consecutive days nor in 2 week old puppies with the same treatment schedule.

Tests indicated no effect on circulating microfilariae or adult heartworms (*Dirofilaria immitis*) when dogs were treated at a daily dosage rate of 15 mg/kg for 30 days. No effect on cholinesterase values was observed.

No adverse effects were observed on reproductive parameters when male dogs received 10 consecutive daily treatments of 15 mg/kg/day at 3 intervals (90, 45 and 14 days) prior to breeding or 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 & 30th days), late pregnancy (between 40th & 60th days), and during lactation (the first 28 days).

Cats: Cats in age ranges of 3 to 4 months and 7 to 10 months received daily treatments of 25 mg/kg for 30 consecutive days with no adverse effects upon the clinical chemistry, hematological or histological parameters. In cats 7-10 months of age treated daily for 30 consecutive days, 2 of 4 receiving 5 mg/kg, 3 of 4 receiving 15 mg/kg, 2 of 4 receiving 25 mg/kg and 1 of 4 nontreated controls experienced occasional vomiting. Five to 7 month old cats had no side effects with daily treatments of 15 mg/kg for 30 days, but 2 of 4 animals had articular cartilage lesions when administered 25 mg/kg/day for 30 days.

Doses of 125 mg/kg for 5 consecutive days to adult cats induced vomiting, depression, incoordination and death while those receiving 50 mg/kg for 6 days had clinical signs of vomiting, inappetence, incoordination and convulsions, but they returned to normal.

#### DRUG INTERACTIONS:

Compounds that contain metal cations (e.g., aluminum, calcium, iron, magnesium) may reduce the absorption of some quinolone-class drugs from the intestinal tract. Concomitant therapy with other drugs that are metabolized in the liver may reduce the clearance rates of the quinolone and the other drug.

Dogs: Enrofloxacin has been administered to dogs at a daily dosage rate of 10 mg/kg concurrently with a wide variety of other health products including anthelmintics (praziquantel, febantel, sodium disphenol), insecticides (fenthion, pyrethrins), heartworm preventatives (diethylcarbamazine) and other antibiotics (ampicillin, gentamicin sulfate, penicillin, dihydrostreptomycin). No incompatibilities with other drugs are known at this time.

Cats: Enrofloxacin was administered at a daily dosage rate of 5 mg/kg concurrently with anthelmintics (praziquantel, febantel), an insecticide (propoxur) and another antibacterial (ampicillin). No incompatibilities with other drugs are known at this time.

#### PRECAUTION:

Quinolone-class drugs should be used with caution in animals with known or suspected Central Nervous System (CNS) disorders. In such animals, quinolones have, in rare instances, been associated with CNS stimulation which may lead to convulsive seizures.

Quinolone-class drugs have been associated with cartilage erosions in weight-bearing joints and other forms of arthropathy in immature animals of various species.

Safety in breeding or pregnant cats has not been established.

#### HUMAN WARNINGS:

For Use in Animals Only. Keep Out of Reach of Children.

Avoid contact with eyes. In case of contact, immediately flush eyes with copious amounts of water for 15 minutes. In case of dermal contact, wash skin with soap and water. Consult a physician if irritation persists following ocular or dermal exposure. Individuals with a history of hypersensitivity to quinolones should avoid this product. In humans, there is a risk of user photosensitization within a few hours after excessive exposure to quinolones. If excessive accidental exposure occurs, avoid direct sunlight.

To report adverse reactions or to obtain a copy of the Material Safety Data Sheet, call 1-800-633-8405.

#### DOSAGE AND ADMINISTRATION:

The dose range of Baytril (brand of enrofloxacin) Taste Tabs™ Tablets in dogs and cats is 5 to 20 mg/kg (2.27-9.07 mg/lb) of body weight, either as a single dose or divided into two (2) equal daily doses administered at twelve (12) hour intervals. Selection of a dose within this range should be based on clinical experience, the severity of disease, and susceptibility of the pathogen.

Palatability: Most dogs will consume Baytril® Taste Tabs™ Tablets willingly when offered by hand. Alternatively, the tablet(s) may be offered in food or hand-administered (pilled) as with other oral tablet medications. In cats, Baytril® Taste Tabs™ Tablets should be pillled. After administration, watch the animal closely to be certain the entire dose has been consumed.

Animals which receive doses in the upper-end of the dose range should be carefully monitored for clinical signs that may include inappetence, depression, and vomiting. For dogs, Baytril Injectable Solution may be used initially as a single intramuscular dose at 2.5 mg/kg.

#### TABLETS:

Dogs & Cats: The duration of treatment should be selected based on clinical evidence. Generally, administration of Baytril Tablets should continue for at least 2-3 days beyond cessation of clinical signs. For severe and/or complicated infections, more prolonged therapy, up to 30 days, may be required. If no improvement is seen within five days, the diagnosis should be reevaluated and a different course of therapy considered.

#### INJECTABLE SOLUTION:

Dogs Only: Baytril Injectable Solution may be used as the initial dose at 2.5 mg/kg. It should be administered intramuscularly (IM) as a single dose, followed by initiation of Baytril Tablet therapy.

Baytril Tablets and Injectable Solution may be administered as follows:

Weight of Animal	Baytril Injectable Solution* (Dogs Only)	Baytril Tablet (Dogs and Cats) Once Daily Dosing Chart			
		5.0 mg/kg	10.0 mg/kg	15.0 mg/kg	20.0 mg/kg
9.1 kg (20 lb)	1.00 mL	2 x 22.7 mg tablets	1 x 22.7 mg plus 1 x 68 mg tablets	1 x 136 mg tablet	1 x 136 mg plus 2 x 22.7 mg tablets
27.2 kg (60lb)	3.00 mL	1 x 136 mg tablet	2 x 136 mg tablets	3 x 136 mg tablets	4 x 136 mg tablets

\* The initial Baytril Injectable administration should be followed 12 hours later by initiation of Baytril Tablet therapy.

All tablet sizes are double scored for accurate dosing.

The lower limit of the dose range was based on efficacy studies in dogs and cats where enrofloxacin was administered at 2.5 mg/kg twice daily. Target animal safety and toxicology studies were used to establish the upper limit of the dose range and treatment duration.

#### STORAGE:

Protect injectable from direct sunlight. Do not freeze.

#### HOW SUPPLIED:

Code Number	Baytril Injectable Solution	Tablets/Bottle	
	22.7 mg/mL Vial Size		
1865	20 mL	100 Double Scored	
Code Number	Baytril Tablets	Tablets/Bottle	
	Tablet Size	100 Double Scored	
	0387	22.7 mg	50 Double Scored
	0388	22.7 mg	50 Double Scored
	0389	68.0 mg	250 Double Scored
	0390	68.0 mg	50 Double Scored
0417	136.0 mg	50 Double Scored	
0391	136.0 mg	200 Double Scored	

U.S. Patent No. 4,670,444

#### REFERENCES:

1 Dougherty, T.J. and Saukkonen, J.J. Membrane Permeability Changes Associated with DNA Gyrase Inhibitors in *Escherichia coli* Antimicrob. Agents and Chemother., V. 28, Aug. 1985, 200-206.

2 Walker, R.D. et al. Pharmacokinetic Evaluation of Enrofloxacin Administered Orally to Healthy Dogs. Am. J. Res. V. 53, No. 12, Dec. 1992; 2315-2319.

Bayer Corporation  
Agriculture Division, Animal Health  
Shawnee Mission, Kansas 66201, U.S.A.

NADA 140-441, Approved by FDA  
NADA 140-913, Approved by FDA

EDP# TBD, R.0

February, 1998

Fit-a-Form Pat. 4488922

0417

EDP# TBD, R.0

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Read package insert carefully for complete details.

**CONTRAINDICATIONS:** The use of enrofloxacin is contraindicated in small and medium breeds of dogs during the rapid growth phase (between 2 and 8 months of age). The safe use of enrofloxacin has not been established in large and giant breeds during the rapid growth phase. Consult package insert for details.

**DOSAGE:** Administer orally at a rate to provide 5-20 mg/kg (2.27 to 9.07 mg/lb) of body weight, either as a single daily dose or divided into two (2) equal daily doses administered at twelve (12) hour intervals. Selection of a dose within this range should be based on clinical experience, the severity of disease, and the susceptibility of the pathogen. This dose should be continued for at least 2-3 days beyond cessation of clinical signs. To a maximum of 30 days. Animals which receive doses at the upper-end of the dose range should be carefully monitored for clinical signs that may include inappetence, depression, or vomiting.

▲ OPEN ALONG PERFORATION ▲

30349