

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):

Administered 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.

III. 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.

IV. 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® Taste Tabs™ 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..

VII. Labeling:

A copy of the labeling is attached to this document.

- A. Baytril (enrofloxacin) Antimicrobial Tablets No. 20, 500 tablet bottle, label
- B. Baytril (enrofloxacin) Antimicrobial Tablets No. 20, 500 tablet bottle, package insert

- C. Baytril (enrofloxacin) Antimicrobial Tablets No. 60, 250 tablet bottle, label
- D. Baytril (enrofloxacin) Antimicrobial Tablets No. 60, 250 tablet bottle, package insert
- E. Baytril (enrofloxacin) Injectable Solution, 20 mL vial, vial label, carton label, package insert