

# Bayer

Agriculture Division

Animal Health  
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Dear Doctor,

Baytril® (enrofloxacin), the first fluoroquinolone developed by Bayer specifically for veterinary use, has been approved for the treatment of bacterial infections in dogs and cats in the United States since 1989 and 1990, respectively. Prior to FDA approval in 1989, Baytril underwent mandatory toxicological testing in dogs and cats. Pre-approval target animal safety studies in both dogs and cats demonstrated safety at 25 mg/kg/day x 30 days.

Bayer Animal Health has received sporadic but an increasing number of reports concerning altered vision in feline patients treated with Baytril Tablets and/or Baytril Injectable. (Baytril Injectable is only approved for use in dogs.) These reports, while uncommon, include blindness, temporary blindness, partial blindness, and mydriasis. Bayer Animal Health estimates that the incidence of vision related reports over the past decade in the U.S. is 0.0008%, or 1 report per 122,414 feline patients treated. The increase in the number of reports appears to be temporally associated with the July 1997 label change for the oral dosage form from a point dose administration of 2.5 mg/kg

bid to the flexible dose administration of 5-20 mg/kg as a single dose or two equally divided doses.

Bayer is taking a number of actions to thoroughly investigate the relationship. As you are aware, there are many causes of acute vision loss in cats. Bayer has enlisted the input and expertise from a panel of veterinary ophthalmologists of the American College of Veterinary Ophthalmology (ACVO) regarding the best means to objectively investigate this matter. On behalf of Bayer Animal Health, we want to ensure you have accurate information on Baytril for the benefit of your practice and your patients.

As a result of our discussions with the ophthalmologists, a specific feline safety study designed to assess any potential effects of Baytril on ocular parameters is underway. This study is being conducted with dosages both within and well above the label dose range by board certified veterinary ophthalmologists. Retinal histopathology will be performed at the conclusion of the study. Upon completion of the study, we will communicate the final results to you.

*However, preliminary results suggest dose related ocular effects. The most severe observations are in cats dosed at 50 mg/kg/day (2.5x the high-end of the approved dose range) and developed within one week. No changes have been observed in cats dosed at 5 mg/kg/day (the lower end of the approved dose range). Therefore, at this time, we strongly recommend to restrict the use of Baytril Tablets in cats at a dose not to exceed 5 mg/kg/day.*

*Again, Baytril® (enrofloxacin) Injectable has only been approved for use in dogs. Discussion with your clients of potential side effects of any medication is always encouraged. We recommend you include in this discussion the potential for possible effects on the retina in cats treated with Baytril.*

Bayer is thoroughly documenting and monitoring all reported cases in order to collect as much salient information as possible. To that end, we ask that any suspected case be reported directly to us. As a responsible manufacturer of drugs for animals and humans, Bayer cares greatly about the safety of all its products and the well being of your patients.

We will continue to provide pertinent information to you and support your commitment to provide quality veterinary care. Please direct any questions about Baytril or any of the Bayer products to Bayer Veterinary Services, 800-422-9874.

/s/

Erin Evans, DVM  
Director, Veterinary Services  
Bayer Corporation