



OTITIS: A Dog Owner's Guide

The term “otitis” can be used to describe a wide variety of problems associated with the ears. All of these can be divided into two basic categories:

- ▶ **Primary** otitis is caused by a problem within the ears themselves. For example, ear mites cause primary otitis; they directly cause discomfort to the pet as they colonize the ears.
- ▶ **Secondary** otitis results from an underlying problem that affects the ears. Allergies are a good example; dogs may scratch and rub their ears because they are generally uncomfortable. When the allergy is treated, the scratching and rubbing stops and the ears improve.

Ear problems are very common in dogs. Bacterial and yeast infections, ear mites, allergies, immune mediated diseases, and tumors are just a few of the many causes. Your veterinarian will want to determine if the otitis is primary or secondary so that an effective treatment plan can be developed.

TREATMENT

In cases of bacterial, yeast, and parasitic infections, you may need to apply medication directly into your pet's ears to kill the organisms responsible. Other topical medications can help decrease pain and redness. Sometimes oral medications may also be prescribed.

It's important that the ears are cleaned before any topical medication is applied. In ears that contain a large amount of discharge, the medication may not be able to get to where it needs to be. Clean your dog's ears only as your veterinarian has instructed. Remember to be gentle when cleaning painful ears. After the ears are clean, apply the amount of medication prescribed by your veterinarian into the opening of the vertical ear canal and *gently* massage it to distribute the medication throughout the entire ear canal.

PREVENTION

The best way to prevent otitis is by keeping your dog's ears clean. Speak to your veterinarian about the types of ear problems likely to be experienced by your dog and other ways to help prevent them.



The part of the ear that extends from the head is called the pinna; it comes in many different shapes and sizes depending on the breed. Inside the ear, there is a vertical canal that opens to the outside and makes an inward 90 degree bend to become the horizontal canal.



Talk with your veterinarian about
Baytril® Otic (enrofloxacin/silver sulfadiazine).

See product information summary on the next page.

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B06137

Baytril® Otic

(enrofloxacin/silver sulfadiazine)

Antibacterial-Antimycotic Emulsion

For Otopical Use In Dogs

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

▶ Federal law prohibits the extralabel use of this drug in food-producing animals. ◀

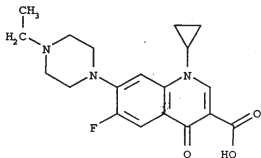
PRODUCT DESCRIPTION:

Each milliliter of Baytril® Otic contains: enrofloxacin 5 mg (0.5% w/v), silver sulfadiazine (SSD) 10 mg (1.0% w/v), benzyl alcohol (as a preservative) and cetylstearyl alcohol (as a stabilizer) in a neutral oil and purified water emulsion. The active ingredients are delivered via a physiological carrier (a nonirritating emulsion).

CHEMICAL NOMENCLATURE AND STRUCTURE:

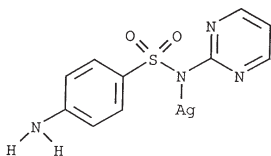
Enrofloxacin

1-Cyclopropyl-7-(4-ethyl-1-piperazinyl)-6-fluoro-1, 4-dihydro-4-oxo-3-quinolonecarboxylic acid.



Silver Sulfadiazine

Benzenesulfonamide, 4-amino-N-2-pyrimidinyl-monosilver



ACTIONS:

Enrofloxacin, a 4-fluoroquinolone compound, is bactericidal with activity against a broad spectrum of both Gram negative and Gram positive bacteria. Fluoroquinolones elicit their bactericidal activities through interactions with two intracellular enzymes, DNA gyrase (DNA topoisomerase II) and DNA topoisomerase IV, which are essential for bacterial DNA transcription, synthesis and replication. It is believed that fluoroquinolones actively bind with bacterial DNA:ENZYME complexes and thereby inhibit the essential processes catalyzed by the enzymes (DNA supercoiling and chromosomal decatenation).¹ The ultimate outcome of the fluoroquinolone intervention is DNA fragmentation and bacterial cell death.^{2,3}

Silver sulfadiazine (SSD) is synthesized from silver nitrate and sodium sulfadiazine.⁴ This compound has a wide spectrum of antimicrobial activity against Gram negative and Gram positive bacteria and is also an effective antimycotic.^{5,6} SSD suppresses microbial growth through inhibition of DNA replication and modification of the cell membrane.

MICROBIOLOGY:

In clinical field trials, Baytril® Otic demonstrated elimination or reduction of clinical signs associated with otitis externa and *in vitro* activity against cultured organisms. Baytril® Otic is effective when used as a treatment for canine otitis externa associated with one or more of the following organisms: *Malassezia pachydermatis*, *coagulase-positive Staphylococcus spp.*, *Pseudomonas aeruginosa*, *Enterobacter spp.*, *Proteus mirabilis*, *Streptococci spp.*, *Aeromonas hydrophila*, *Aspergillus spp.*, *Klebsiella pneumoniae*, and *Candida albicans*.

In vitro assays, such as disk-diffusion and agar/broth-dilution, are used to determine the susceptibilities of microbes to antimicrobial therapies. Results of agar/broth-dilution assays are reported as a Minimal Inhibitory Concentration (MIC) which represents the lowest antimicrobial concentration, expressed in µg/mL, capable of inhibiting the growth of a pathogenic microorganism. MICs are used in conjunction with pharmacokinetics to predict the *in vivo* efficacy of systemically administered antimicrobials. Topical administration of Baytril® Otic to an exudate and debris-free canal, however, will generally result in local antimicrobial concentrations that greatly exceed serum and tissue levels resulting from systemic therapy. Therefore, when using Baytril® Otic as a treatment for canine otitis externa, interpret susceptibility data cautiously.

INDICATIONS:

Baytril® Otic is indicated as a treatment for canine otitis externa complicated by bacterial and fungal organisms susceptible to enrofloxacin and/or silver sulfadiazine (see Microbiology section).

EFFECTIVENESS:

Due to its combination of active ingredients, Baytril® Otic provides antimicrobial therapy against bacteria and fungi (which includes yeast) commonly encountered in cases of canine otitis externa.

The effectiveness of Baytril® Otic was evaluated in a controlled, double-blind, multi-site clinical trial. One hundred and sixty-nine dogs (n=169), with naturally occurring active otitis externa participated in the study. The presence of active disease was verified by aural cytology, microbial culture and otoscopy/clinical scoring. Qualified cases were randomly assigned to either Baytril Otic treatment (n=113) or to a comparable placebo-based regimen (n=56). Treatments were administered twice daily for up to 14 days. Assessment of effectiveness was based on continued resolution of clinical signs 3 to 4 days following administration of the last dose.

At study conclusion, Baytril® Otic was found to be a significantly more effective treatment for canine otitis externa than the placebo regimen. Based on the scoring system used to assess treatment response, therapeutic success occurred in 67% of Baytril® Otic-treated infections compared to 14% with placebo (r-value² 0.001) after 14 days of treatment.

CONTRAINDICATIONS:

Baytril® Otic is contraindicated in dogs with suspected or known hypersensitivity to quinolones and/or sulfonamides.

HUMAN WARNINGS:

Not for human use. Keep out of the 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 develops or persists following ocular or dermal exposures. Individuals with a history of hypersensitivity to quinolone compounds or antibacterials should avoid handling 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.

PRECAUTIONS:

The use of Baytril® Otic in dogs with perforated tympanic membranes has not been evaluated. Therefore, the integrity of the tympanic membrane should be evaluated before administering this product. If hearing or vestibular dysfunction is noted during the course of treatment, discontinue use of Baytril® Otic.

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 weightbearing joints and other forms of arthropathy in immature animals of various species.

The safe use of Baytril® Otic in dogs used for breeding purposes, during pregnancy, or in lactating bitches, has not been evaluated.

ADVERSE REACTIONS:

During clinical trials, 2 of 113 (1.7%) dogs exhibited reactions that may have resulted from treatment with Baytril® Otic. Both cases displayed local hypersensitivity responses of the aural epithelium to some component within the Baytril® Otic formulation. The reactions were characterized by acute inflammation of the ear canal and pinna.

For medical emergencies or to report adverse reactions, call 1-800-422-9874. For customer service or to obtain product information, including Material Safety Data Sheet, call 1-800-633-3796.

SAFETY:

General Safety Study:

In a target animal safety study, Baytril® Otic was administered in both ears of 24 clinically normal beagle dogs at either recommended or exaggerated dosages: 10, 30 or 50 drops applied twice daily for 42 consecutive days. A control group of 8 beagle dogs was treated by administering 50 drops of vehicle in one ear twice daily for 42 consecutive days, with the contralateral ear untreated. Erythema was noted in all groups, including both treated and untreated ears in the controls, which resolved following termination of treatment.

Oral Safety Study:

In order to test safety in case of ingestion, Baytril® Otic was administered, twice daily for 14 consecutive days, to the dorsum of the tongue and to the left buccal mucosa of 6 clinically normal dogs. No adverse local or systemic reactions were reported.

DOSAGE AND ADMINISTRATION:

Shake well before each use.

Tilt head so that the affected ear is presented in an upward orientation. Administer a sufficient quantity of Baytril® Otic to coat the aural lesions and the external auditory canal. As a general guide, administer 5-10 drops per treatment in dogs weighing 35 lbs. or less and 10-15 drops per treatment in dogs weighing more than 35 lbs. Following treatment, gently massage the ear so as to ensure complete and uniform distribution of the medication throughout the external ear canal. Apply twice daily for a duration of up to 14 days.

STORAGE:

Store between 4° and 25°C (40 - 77°F). Store in an upright position. Do not store in direct sunlight.

HOW SUPPLIED:

Baytril® Otic (enrofloxacin/silver sulfadiazine)

Code Number	Size	Presentation	
08711529-042099	15 mL	Oval plastic bottle with per tip and extended tip closure	drop-
08711537-042199	30 mL	Oval plastic bottle with per tip and extended tip closure	drop-

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