

R otic suspension (miconazole nitrate, polymyxin B sulfate, prednisolone acetate)

Antifungal, antibacterial and anti-inflammatory
For otic use in dogs only

CAUTION

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

DESCRIPTION

SUROLAN contains 23 mg/mL miconazole nitrate, 0.5293 mg/mL polymyxin B sulfate and 5 mg/mL prednisolone acetate. Inactive ingredients are colloidal silicon dioxide and liquid paraffin.

INDICATIONS

SUROLAN is indicated for the treatment of canine otitis externa associated with susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Staphylococcus pseudintermedius*).

DOSAGE AND ADMINISTRATION

Shake well before use.

The external ear should be thoroughly cleaned and dried before the initiation of treatment. Verify that the eardrum is intact. Instill 5 drops of SUROLAN in the ear canal twice daily and massage the ear. Therapy should continue for 7 consecutive days.

CONTRAINDICATIONS

SUROLAN is contraindicated in dogs with suspected or known hypersensitivity to miconazole nitrate, polymyxin B sulfate, or prednisolone acetate. Do not use in dogs with known perforated tympanum. Do not use with drugs known to induce ototoxicity.

WARNINGS

Not for use in humans. Keep this and all drugs out of reach of children.

ANIMAL WARNINGS

Do not administer orally.
For otic use only.

PRECAUTIONS

Before instilling any medication into the ear, examine the external ear canal thoroughly to be certain the tympanic membranes are not ruptured. If overgrowth of non-susceptible bacteria or fungi occurs, treatment should be discontinued and appropriate therapy instituted. Long-term use of topical otic corticosteroids has been associated with adrenocortical suppression and iatrogenic hypoadrenalism in dogs. The safe use of SUROLAN in dogs used for breeding purposes, during pregnancy, or in lactating bitches, has not been evaluated.

ADVERSE REACTIONS

In the field study, 161 dogs treated with SUROLAN were included in the safety database. Two dogs experienced reduced hearing at the end of treatment; on follow-up one dog had normal hearing capacity while the other case was lost for follow-up. The owner of another dog reported that on day 4 of treatment, build-up of the medication decreased the dog's hearing. At the end of treatment, this dog had normal hearing as assessed by the investigator. Residue build-up was reported in 1 dog and pain upon drug application in another dog. A total of 161 dogs treated with the active control was included in the safety database and adverse reactions were reported in 8 dogs treated with the active control. One dog experienced reduced hearing at the end of treatment. Residue build-up was noted in 1 dog. Four dogs vomited during treatment, 1 dog showed red pustules on the pinna and head shaking was observed in another dog. Foreign market experience: the following adverse events were reported voluntarily during post-approval use of the product in foreign markets: deafness, reduced hearing, topical hypersensitivity reactions and red blisters on pinna.

For a copy of the Material Safety Data Sheet (MSDS), for technical assistance or to report a suspected adverse drug reaction, contact Elanco Animal Health at 1-888-545-5973. Alternatively, suspected adverse drug reactions may be reported to FDA at 1-888-FDA-VETS or www.fda.gov/reportanimalae

PHARMACOLOGY

By virtue of its 3 active ingredients, SUROLAN has antibacterial, antifungal, and anti-inflammatory activity. **Polymyxin B sulfate** is a broad-spectrum polypeptide antibiotic with activity against both Gram-positive and Gram-negative species. **Miconazole nitrate** is a synthetic imidazole derivative with antifungal activity and antibacterial activity against Gram-positive bacteria. Moreover, synergistic effects between miconazole nitrate and polymyxin B sulfate have been demonstrated in an *in vitro* study⁽¹⁾. **Prednisolone acetate** is a glucocorticoid with anti-inflammatory activity. A study performed using an experimentally-induced model of ear inflammation in mice demonstrated the effectiveness of prednisolone acetate in treating ear inflammation either alone or in combination with the other active ingredients of SUROLAN⁽²⁾.

MICROBIOLOGY

The compatibility and additive effect of each of the components in SUROLAN was demonstrated in a component effectiveness and non-interference study. An *in vitro* study of organisms collected from clinical cases of otitis externa at a veterinary teaching hospital and from dogs enrolled in the clinical effectiveness study for SUROLAN determined that polymyxin B sulfate and miconazole nitrate inhibit the growth of bacteria and yeast commonly associated with canine otitis externa. Furthermore, a synergistic effect of the two antimicrobials was demonstrated. The addition of prednisolone acetate to the combination did not impair antimicrobial activity to any clinically-significant extent.

ANIMAL SAFETY

The following adverse reactions were reported in a study when SUROLAN was administered at 1X, 3X and 5X for 42 consecutive days (6 times the recommended treatment duration) in laboratory Beagles: hypersensitivity reactions which included mild erythema and hyperemia, painful and sensitive ear canals on examination, changes in hematology, clinical chemistry and urinalysis values consistent with the systemic absorption of topical corticosteroids, and veterinary observations of pale ear canals.

EFFECTIVENESS

Of 337 dogs enrolled in the field study, 176 dogs were included in the effectiveness database; 91 were treated with SUROLAN and 85 were treated with an FDA-approved active control. Clinical evaluations of otitis externa included pain/discomfort, swelling, redness, and exudate. A non-inferiority evaluation was used to compare SUROLAN with the active control with respect to each clinical sign of otitis externa and overall clinical improvement. SUROLAN was determined to be non-inferior to treatment with the active control for otitis externa. *Malassezia pachydermatis* and *Staphylococcus pseudintermedius* were identified pre-treatment in at least 10 cases that were clinically responsive to SUROLAN.

Table 1. Mean Percentage of Improvement in Clinical Signs of Otitis Externa

Clinical sign	SUROLAN N=91	Active control N=85
Pain/discomfort	94.4%	91.7%
Swelling	89.1%	90.5%
Redness	91.2%	86.1%
Exudate	83.1%	82.1%
Overall	96.7%	95.2%

HOW SUPPLIED

SUROLAN is available in 15 mL and 30 mL plastic dispensing bottles with applicator tip for otic use.

STORAGE AND HANDLING

Store at or below 25 °C (77 °F).

Approved by FDA under NADA # 141-298

Manufactured for Elanco US, Inc.,
Greenfield, IN 46140

Product of Portugal

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NDC 0986-0813-15
NDC 0986-0813-30
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CA081330HAM

July 2019

REFERENCES

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Synergistic effects of miconazole and polymyxin B on microbial pathogens.
Veterinary Research Communications 33(6), 489-505
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In vivo efficacy study of the anti-inflammatory properties of Surolan
The Canadian Journal of Veterinary Research
70, 234-236





Baytril® Otic

(enrofloxacin/silver sulfadiazine)

Antibacterial-Antimycotic Emulsion

For Otopotical 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.

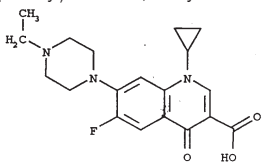
PRODUCT DESCRIPTION:

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:

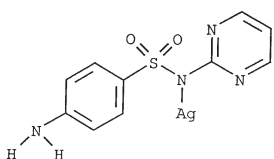
Enrofloxacin

1-Cyclopropyl-7-(4-ethyl-1-piperazinyl)-6-fluoro-1, 4-dihydro-4-oxo-3-quinolinecarboxylic 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)

Size	Presentation
15 mL	Oval plastic bottle with dropper tip and extended tip closure

REFERENCES:

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- Gootz TD and Brightly KE. Fluoroquinolone antibacterial: mechanism of action, resistance and clinical aspects. Medicinal Research Reviews 1996; 16 (5): 433-486.
- Drica K and Zhao X. DNA gyrase, topoisomerase IV and the 4-quinolones. Microbiology and Molecular Biology Reviews 1997; 61(3): 377-392.
- Fox CL. Silver sulfadiazine: a new topical therapy for *Pseudomonas* in burns. Archives of Surgery 1968; 96:184-188.
- Wlodkowski TJ and Rosenkranz HS. Antifungal activity of silver sulfadiazine. Lancet 1973; 2:739-740.
- Schmidt A. *In vitro* activity of clotrimazole, clotrimazole and silver sulfadiazine against isolates of *Malassezia pachydermatis*. J of Vet Medicine Series B 1997; 44: 193-197.

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LV1902

Bayer



(florfenicol, terbinafine, mometasone furoate) Otic Solution for use in dogs only

Do Not Use in Cats.

Antibacterial, antifungal, and anti-inflammatory

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

DESCRIPTION:

CLARO® contains 16.6 mg/mL florfenicol, 14.8 mg/mL terbinafine (equivalent to 16.6 mg/mL terbinafine hydrochloride) and 2.2 mg/mL mometasone furoate. Inactive ingredients include purified water, propylene carbonate, propylene glycol, ethyl alcohol, and polyethylene glycol.

INDICATIONS:

CLARO® is indicated for the treatment of otitis externa in dogs associated with susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Staphylococcus pseudintermedius*).

DOSAGE AND ADMINISTRATION:

CLARO® should be administered by veterinary personnel.

Wear eye protection when administering CLARO®. (see **Human Warnings, PRECAUTIONS, POST APPROVAL EXPERIENCE**).

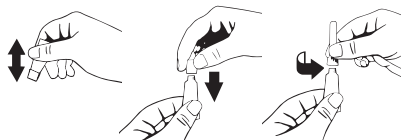
Splatter may occur if the dog shakes its head following administration. Persons near the dog during administration should also take steps to avoid ocular exposure.

Shake before use.

Verify the tympanic membrane is intact prior to administration. (see **CONTRAINDICATIONS, PRECAUTIONS, POST APPROVAL EXPERIENCE**).

Administer one dose (1 dropperette) per affected ear.

1. Clean and dry the external ear canal before administering the product.
2. Verify the tympanic membrane is intact prior to administration.
3. Remove single dose dropperette from the package.
4. While holding the dropperette in an upright position, remove the cap from the dropperette.
5. Turn the cap over and push the other end of the cap onto the tip of the dropperette.
6. Twist the cap to break the seal and then remove cap from the dropperette.
7. Screw the applicator nozzle onto the dropperette.



8. Insert the tapered tip of the dropperette into the affected external ear canal and squeeze to instill the entire contents (1 mL) into the affected ear.
9. Gently massage the base of the ear to allow distribution of the solution.
Restrain the dog to minimize post application head shaking to reduce potential for splatter of product and accidental eye exposure in people and dogs (see **POST APPROVAL EXPERIENCE**).
10. Repeat with other ear as prescribed.
11. The duration of the effect should last 30 days. Cleaning the ear after dosing may affect product effectiveness.



CONTRAINDICATIONS:

Do not use in dogs with known tympanic membrane perforation (see **PRECAUTIONS**).

CLARO® is contraindicated in dogs with known or suspected hypersensitivity to florfenicol, terbinafine hydrochloride, or mometasone furoate.

WARNINGS:

Human Warnings: CLARO® may cause eye injury and irritation (see **PRECAUTIONS, POST APPROVAL EXPERIENCE**).

If contact with eyes occurs, flush copiously with water for at least 15 minutes. If irritation persists, contact a physician.

Humans with known hypersensitivity to any of the active ingredients in CLARO® should not handle this product.

Not for use in humans. Keep this and all drugs out of the reach of children. Avoid skin contact. In case of accidental ingestion by humans, contact a physician immediately.

PRECAUTIONS:

For use in dogs only. Do not use in cats (see **POST APPROVAL EXPERIENCE**).

Wear eye protection when administering CLARO® and restrain the dog to minimize post application head shaking. Reducing the potential for splatter of product will help prevent accidental eye exposure in people and dogs and help to prevent ocular injury (see **DOSAGE AND ADMINISTRATION, Human Warnings, POST APPROVAL EXPERIENCE**).

Proper patient selection is important when considering the benefits and risks of using CLARO®.

The integrity of the tympanic membrane should be confirmed before administering the product.

CLARO® has been associated with rupture of the tympanic membrane. Reevaluate the dog if hearing loss or signs of vestibular dysfunction are observed during treatment.

Signs of internal ear disease such as head tilt, vestibular signs, ataxia, nystagmus, facial paralysis, and keratoconjunctivitis sicca have been reported (see **POST APPROVAL EXPERIENCE**) with the use of CLARO®. Do not administer orally.

Use of topical otic corticosteroids has been associated with adrenocortical suppression and iatrogenic hyperadrenocorticism in dogs (see **ANIMAL SAFETY**).

Use with caution in dogs with impaired hepatic function (see **ANIMAL SAFETY**).

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

ADVERSE REACTIONS:

In a field study conducted in the United States (see **EFFECTIVENESS**), there were no directly attributable adverse reactions in 146 dogs administered CLARO®.

POST APPROVAL EXPERIENCE (2019):

The following adverse events are based on post-approval adverse drug experience reporting for CLARO®. Not all adverse events are reported to FDA/CVM. It is not always possible to reliably estimate the adverse event frequency or establish a causal relationship to product exposure using these data.

In **humans**, accidental exposure leading to corneal ulcers and other ocular injuries such as eye irritation and redness have been reported. Exposure occurred when the dog shook its head after application of CLARO®. Skin irritation has also been reported.

In **dogs**, the adverse events reported are presented below in decreasing order of reporting frequency: Ear discharge, head shaking, ataxia, internal ear disorder (head tilt and vestibular), deafness, emesis, nystagmus, pinna irritation and ear pain, keratoconjunctivitis sicca, vocalization, corneal ulcer, cranial nerve disorder (facial paralysis), tympanic membrane rupture.

CLARO® is not approved for use in **cats**. The adverse events reported following extra-label use in **cats** are presented below in decreasing order of reporting frequency:

Ataxia, anorexia, internal ear disorder (head tilt and vestibular), Horner's syndrome (third eyelid prolapse and miosis), nystagmus, lethargy, anisocoria, head shake, emesis, tympanic rupture, and deafness.

To report suspected adverse drug events and/or obtain a copy of the Safety Data Sheet (SDS) or for technical assistance, contact Elanco at 1-800-422-9874.

For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at <http://www.fda.gov/reportanimalae>.

Information for Dog Owners:

Owners should be aware that adverse reactions may occur following administration of CLARO® and should be instructed to observe the dog for signs such as ear pain and irritation, vomiting, head shaking, head tilt, incoordination, eye pain and ocular discharge (see **POST APPROVAL EXPERIENCE**). Owners should be advised to contact their veterinarian if any of the above signs are observed.

Owners should also be informed that splatter may occur if the dog shakes its head following administration of CLARO® which may lead to ocular exposure. Eye injuries, including corneal ulcers, have been reported in humans and dogs associated with head shaking and splatter following administration. Owners should be careful to avoid ocular exposure (see **PRECAUTIONS, POST APPROVAL EXPERIENCE**).

PHARMACOLOGY:

CLARO® Otic Solution is a fixed combination of three active substances: florfenicol (antibacterial), terbinafine (antifungal), and mometasone furoate (steroidal anti-inflammatory). Florfenicol is a bacteriostatic antibiotic which acts by inhibiting protein synthesis. Terbinafine is an antifungal which selectively inhibits the early synthesis of ergosterol. Mometasone furoate is a glucocorticosteroid with anti-inflammatory activity.

MICROBIOLOGY:

The compatibility and additive effect of each of the components in CLARO® solution was demonstrated in a component effectiveness and non-interference study. An *in vitro* study of organisms collected from clinical cases of otitis externa in dogs enrolled in the clinical effectiveness study determined that florfenicol and terbinafine hydrochloride inhibit the growth of bacteria and yeast commonly associated with otitis externa in dogs. No consistent synergistic or antagonistic effect of the two antimicrobials was demonstrated. The addition of mometasone furoate to the combination did not impair antimicrobial activity to any clinically significant extent. In a field study (see **EFFECTIVENESS**), at least 10 isolates from successfully treated cases were obtained for *S. pseudintermedius* and *M. pachydermatis*.

EFFECTIVENESS:

In a well-controlled, double-masked field study, CLARO® was evaluated against a vehicle control in 221 dogs with otitis externa. One hundred and forty six dogs were treated with CLARO® and 75 dogs were treated with the vehicle control. All dogs were evaluated for safety. Treatment (1 mL) was administered once on Day 0 to the affected ear(s). Prior to treatment, the ear(s) was cleaned with saline. The dogs were evaluated on Days 0, 7, 14, and 30. Blood work and urinalysis were obtained on Day 0 pre-treatment and Day 30 at study completion. Four clinical signs associated with otitis externa were evaluated: erythema, exudate, swelling, and ulceration. Success was based on clinical improvement at Day 30. Of the 183 dogs included in the effectiveness evaluation, 72.5% of dogs administered CLARO® solution were successfully treated, compared to 11.1% of the dogs in the vehicle-control group ($p = 0.0001$).

ANIMAL SAFETY:

In a target animal safety study, CLARO® was administered aurally to 12-week-old Beagle puppies (4 dogs/sex/group) at 0X, 1X, 3X, and 5X the recommended dose once every 2 weeks for a total dosing period of 28 days (3 times the treatment duration). No clinically relevant treatment-related findings were noted in hearing tests, body weight, weight gain, or food consumption. CLARO® administration was associated with post-treatment ear wetness or clear aural exudate, increased absolute neutrophil count, decreased absolute lymphocyte and eosinophil counts, suppression of the adrenal cortical response to ACTH-stimulation, decreased adrenal weight and atrophy of the adrenal cortex, increased liver weight with hepatocellular enlargement/cytoplasmic change, and decreased thymus weight. Other potentially treatment-related effects included mild changes to AST, total protein, inorganic phosphorus, creatinine, and calcium.

STORAGE INFORMATION:

Store between 20°C – 25°C (68°F – 77°F), excursions are permitted 15°C – 30°C (59°F – 86°F).

HOW SUPPLIED:

CLARO® solution is supplied in a single-use dropperette in a blister.

Each dropperette contains one 1 mL dose.

CLARO® is available in cartons of two, ten, or twenty dropperettes.

Manufactured for

Elanco US Inc

Shawnee, KS 66216

Made in Germany

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