



(hydrocortisone aceponate, miconazole nitrate, gentamicin sulfate)  
Otic Suspension for Dogs  
Anti-inflammatory, antifungal, and antibacterial

**Rx**  
For Otic Use in Dogs Only

**CAUTION**  
Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**DESCRIPTION**  
EASOTIC® Otic Suspension contains 1.11 mg/mL hydrocortisone aceponate, 17.4 mg/mL miconazole nitrate and 1.5 mg/mL gentamicin (as sulfate). The inactive ingredient is a semi-liquid petroleum jelly.

**INDICATIONS**  
EASOTIC Otic Suspension 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**  
Verify that the tympanic membrane is intact. **Shake well before each use.**

**Priming the canister:** Prior to the first use of the dosing container, press firmly on the pump several times until the product fills the nozzle (canula tip) with a full dose of product.

Carefully insert the canula into the affected external ear canal(s) and apply 1 mL (a single pump) of Otic Suspension once per day for 5 days. Wash hands after usage.

**CONTRAINDICATIONS**  
Do not use in dogs with known tympanic membrane perforation.

EASOTIC Otic Suspension is contraindicated in dogs with known or suspected hypersensitivity to corticosteroids, imidazole antifungals, or aminoglycoside antibiotics.

**WARNINGS**  
**Human Warnings:** Not for use in humans. Keep this and all drugs out of reach of children. In case of accidental skin contact, wash area thoroughly with water. Avoid contact with eyes.

Humans with known or suspected hypersensitivity to hydrocortisone, aminoglycoside antibiotics, orazole antifungals should not handle this product.

In case of accidental ingestion by humans, contact a physician immediately. Physicians may contact a Poison Control Center for advice concerning cases of ingestion by humans.

**Animal Warnings:** As a class, aminoglycoside antibiotics are associated with ototoxicity, vestibular dysfunction and renal toxicity. The use of EASOTIC Otic Suspension in a dog with a damaged tympanic membrane can result in damage to the structures of the ear associated with hearing and balance or in transmission of the infection to the middle or inner ear. Immediately discontinue use of EASOTIC Otic Suspension if hearing loss or signs of vestibular dysfunction are observed during treatment (see **ADVERSE REACTIONS**).

**PRECAUTIONS**  
Do not administer orally.

Concurrent administration of potentially ototoxic drugs should be avoided.

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

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

The safe use of EASOTIC Otic Suspension 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 adverse reactions reported in 145 dogs administered EASOTIC Otic Suspension.

In foreign market experience, reports of hearing loss and application site erythema have been received. In most reported cases, the hearing loss and erythema were transient and resolved with discontinuation of EASOTIC® suspension.

To report suspected adverse drug events, contact Virbac AH, Inc at 1-800-338-3659 or the FDA at 1-888-FDA-VETS or [www.fda.gov/reportanimalae](http://www.fda.gov/reportanimalae).

For technical assistance or to obtain a Safety Data Sheet, call Virbac at 800-338-3659 or visit us at [us.virbac.com](http://us.virbac.com).

**PHARMACOLOGY**  
Hydrocortisone aceponate is a glucocorticoid with anti-inflammatory effects. Miconazole nitrate is an imidazole antifungal. Gentamicin sulfate is an aminoglycoside antibiotic.

In the target animal safety study, hydrocortisone aceponate, miconazole and gentamicin were shown to be systemically absorbed from the ears of healthy dogs (see **ANIMAL SAFETY**); increased systemic absorption may be observed in inflamed ears.

**MICROBIOLOGY**  
The compatibility and additive effect of each of the components in EASOTIC® Otic Suspension 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 and from dogs enrolled in the clinical effectiveness study for EASOTIC Otic Suspension determined that miconazole nitrate and gentamicin sulfate 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 hydrocortisone aceponate to the combination did not impair antimicrobial activity to any clinically-significant extent.

In a field study (see **EFFECTIVENESS**), the minimum of 10 isolates from successfully treated cases was met for *S. pseudintermedius* and *M. pachydermatis*.

**EFFECTIVENESS**  
The effectiveness of this drug was evaluated in 157 dogs with otitis externa. The study was a double-masked field study with a placebo control. One hundred and four dogs were treated with EASOTIC Otic Suspension and 53 dogs were treated with the placebo control. Treatment was administered once daily for 5 consecutive days to the affected ear(s). The dogs were evaluated at 4 different intervals over the course of 1 month to determine response to therapy. The 6 clinical signs evaluated were: malodor, aural discharge, pruritus, erythema, swelling and pain. The individual clinical scores were assigned based on the severity of each sign. Success was based on clinical improvement at Day 28 ±2 days. The success rates of the 2 groups were significantly different (p=0.0179); 68.5% of dogs administered EASOTIC Otic Suspension were successfully treated, compared to 21.8% of the dogs in the placebo control group.

**ANIMAL SAFETY**  
In the target animal safety study, EASOTIC Otic Suspension was administered at 0X, 1X, 3X and 5X the recommended dose for 15 consecutive days (3 times the recommended treatment duration) in laboratory Beagles, with 8 dogs per group. Hypersensitivity reactions in the external ear canal and inner pinnae were seen in all EASOTIC Otic Suspension groups and included mild to severe aural erythema (3X group), papules and ulceration (1X and 5X groups), otitis externa (3X and 5X groups), and otitis media (5X group). Renal tubular crystals were present in the cortex and medulla (0X, 1X, 3X, and 5X groups) and mild renal tubular basophilia and atrophy were present in one 5X group dog. Baseline cortisol values and the cortisol response to ACTH stimulation were lower in treated dogs compared to the control dogs. The ACTH stimulation test results are consistent with systemic absorption of topical corticosteroids causing suppression of the hypothalamic-pituitary-adrenal axis. Dogs in the 3X and 5X groups demonstrated elevations in AST and ALP, while dogs in the 1X, 3X, and 5X groups had elevated cholesterol, total protein, and albumin levels. Dogs in the 3X and 5X groups also had higher liver weights and greater food consumption.

**STORAGE INFORMATION:** Store at temperatures between 20° C-25° C (68° F-77° F), with excursions permitted between 15° C-30° C (59° F-86° F).

**HOW SUPPLIED:** EASOTIC Otic Suspension is supplied in a polyethylene canister, with a soft applicator canula.

Each canister contains ten 1 mL doses. Made in the U.S.A.

Distributed by:  
Virbac AH, Inc.  
P.O. Box 162059  
Fort Worth, TX 76161 USA



Approved by FDA under NADA # 141-330

Revision Date 04/2020

© 2022 Virbac Corporation. All Rights Reserved. EASOTIC is a registered trademark of Virbac S.A. All other trademarks cited are the property of their respective owners. 1/22 380021



(hydrocortisone aceponate, miconazole nitrate, gentamicin sulfate)

Otic Suspension For Dogs

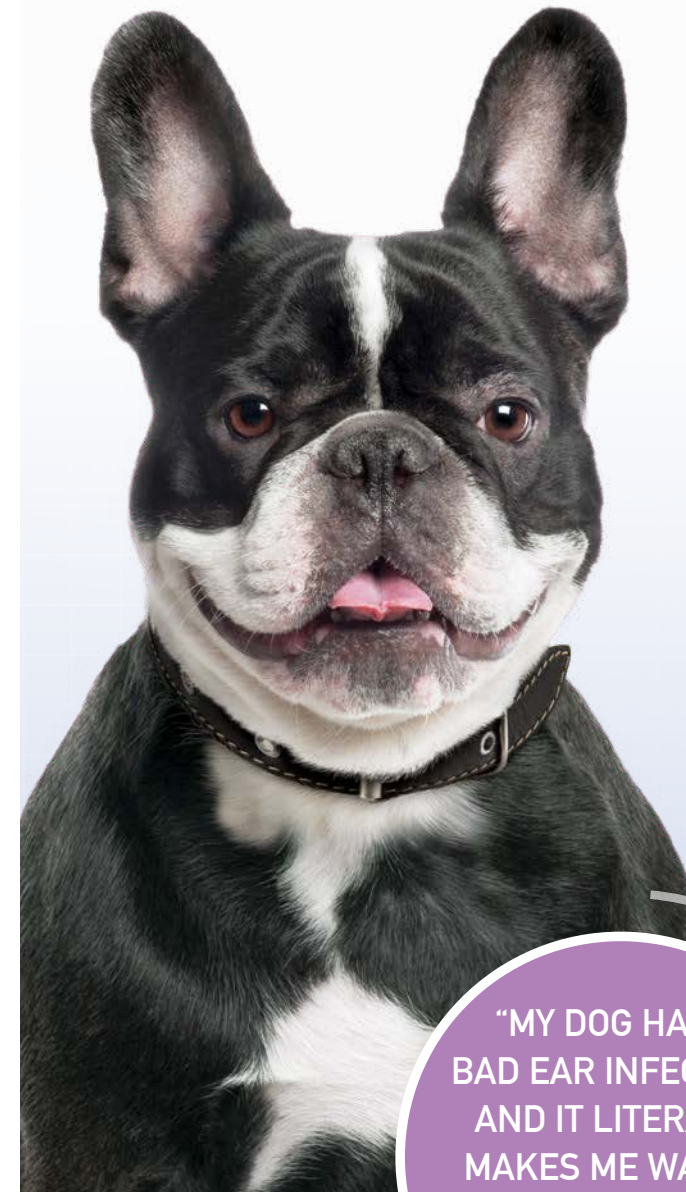
# Take 5

CUSTOMER EXPERIENCE

program

Pet owners reported **rapid relief** and **sustained resolution** of signs, along with **high levels of satisfaction**

A closer look at otitis externa, a common and painful inflammatory disease<sup>1,2</sup>



"MY DOG HAS A BAD EAR INFECTION, AND IT LITERALLY MAKES ME WANNA CRY SEEING HIM SO MISERABLE AND SAD."<sup>3</sup>

— Owner of dog with otitis externa

**Virbac** Shaping the future of animal health

## Research shows that ear infections can be highly emotional for pet owners<sup>3\*</sup>

The Relative Insight platform used a proven methodology to identify similarities and differences in dialogue between audiences, and allows us to understand the topics, languages, and emotions that resonate most strongly with each audience. In this study, the topic was ear infections, and results provided important insights about communication gaps between pet owners and veterinarians and opportunities for better managing pet owner expectations and setting them up for treatment success.

Insights from the research:

- Pet owners find ear infections in their dog emotionally draining and frustrating
- They often feel a sense of urgency and think the therapy recommended takes too long to relieve discomfort and that it's difficult to administer correctly
- Recurrent ear infections are especially discouraging for pet owners

## Pet owners were **3.4x more likely** than veterinarians to use highly emotional words when discussing ear infections<sup>3</sup>

**“MY DOG HAS AN EAR INFECTION AND I’M STRUGGLING TO GET THE OINTMENT INTO HIS EAR. ANY TIPS? STRESS LEVELS VERY HIGH AROUND HERE TODAY!”**

**“MY DOG HAS AN EAR INFECTION AND IS JUST LAYING IN MY BED CRYING. I’M SO UPSET—WHAT CAN I DO TO HELP HER?”**



## HCA—a potent, new-generation, anti-inflammatory drug

Hydrocortisone aceponate (HCA) is a highly lipophilic diester topical steroid that delivers:

- Rapid absorption: 60 times more lipophilic (fat soluble) than hydrocortisone resulting in quick and effective dose concentrations reached in epidermis and dermis<sup>4</sup>
  - Once HCA reaches systemic circulation, most has been converted to a less potent form—hydrocortisone<sup>4</sup>
- A high benefit/risk ratio with a low risk of systemic side effects<sup>4-6</sup>

## A UNIQUE VOLUME-DOSE-POTENCY COMBINATION

The strong safety and benefit/risk profile of HCA in EASOTIC® (hydrocortisone aceponate, miconazole nitrate, gentamicin sulfate) Otic Suspension for Dogs allows it to be administered at over twice the total delivered dose of other Class III glucocorticoids. Lower potency (Class I) glucocorticoids have a smaller benefit/risk ratio yet require higher total delivered doses. This feature helps EASOTIC Otic Suspension for Dogs deliver an excellent anti-inflammatory response.<sup>4,7-14</sup>

Product	Daily volume per label	Administration frequency	Daily dose of glucocorticoid	Total glucocorticoid administered per treatment period	Potency <sup>4</sup> (glucocorticoid class)
<b>EASOTIC® (hydrocortisone aceponate, miconazole nitrate, gentamicin sulfate) Otic Suspension for Dogs<sup>7</sup></b>	1 mL	Once daily for 5 days	<b>1110 µg/day over 5-day treatment</b>	5550 µg	III
<b>Otomax® (gentamicin sulfate, betamethasone valerate, clotrimazole)<sup>8</sup></b>	Dogs < 15 kg: 8 drops = 0.2 mL Dogs > 15 kg: 16 drops = 0.4 mL	Twice daily for 7 days	178 µg/day over 7-day treatment 357 µg/day over 7-day treatment	1249 µg 2498 µg	III
<b>Posatex® Otic Suspension (orbifloxacin, mometasone furoate, posaconazole)<sup>9,10</sup></b> and <b>Mometamax® (gentamicin sulfate, mometasone furoate monohydrate, and clotrimazole, otic suspension)<sup>11</sup></b>	Dogs < 15 kg: 4 drops = 0.1 mL Dogs > 15 kg: 8 drops = 0.2 mL	Once daily for 7 days	108 µg/day over 7-day treatment 216 µg/day over 7-day treatment	756 µg 1512 µg	III
<b>CLARO® (florfenicol, terbinafine, mometasone furoate) Otic Solution<sup>12</sup></b>	1 mL	One-time treatment effective for 30 days	73 µg/day over 30-day treatment	2200 µg	III
<b>OSURNIA® (florfenicol, terbinafine, betamethasone acetate) Otic gel for dogs<sup>13</sup></b>	1 mL	2 doses at 7-day intervals	143 µg/day over 14-day treatment	2000 µg	III
<b>Surolan® (miconazole nitrate, polymyxin B sulfate, prednisolone acetate) Otic Suspension<sup>14</sup></b>	10 drops = 0.22 mL	Twice daily for 7 days	1111 µg/day over 7-day treatment	7778 µg	I

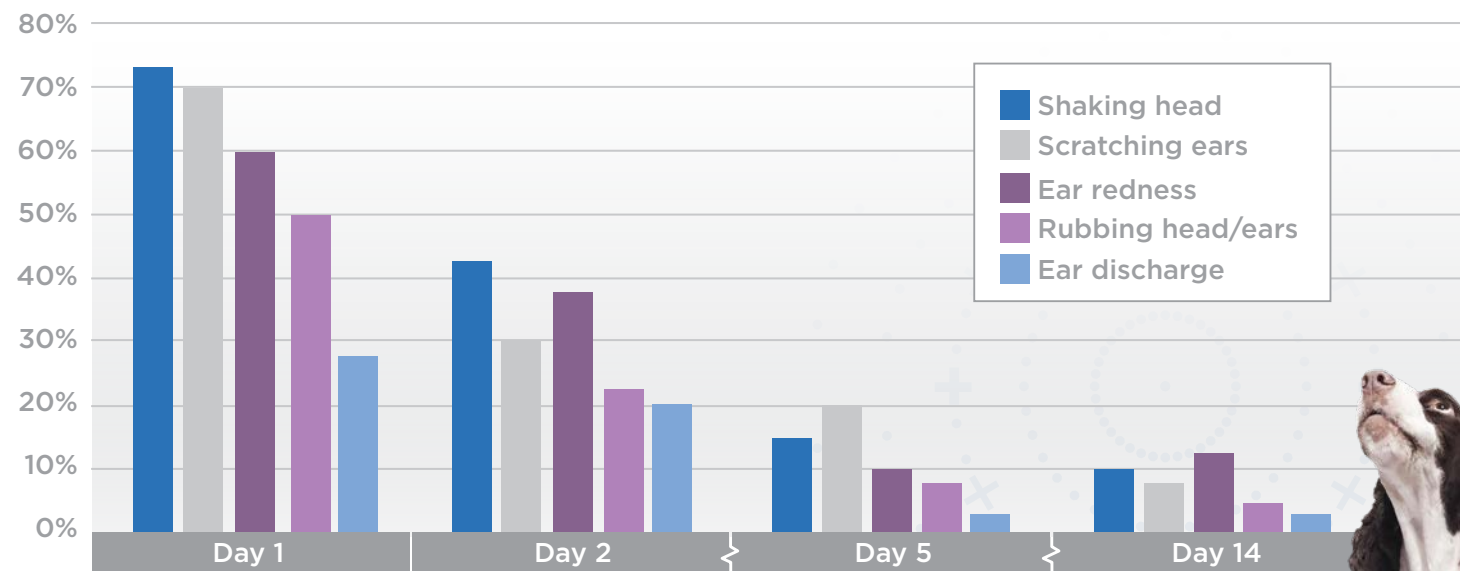
Not for use in dogs with known tympanic membrane (ear drum) perforation. The safe use of EASOTIC Otic Suspension for Dogs in dogs used for breeding purposes has not been evaluated.

# Results of the Take 5 customer experience program<sup>3</sup>

## About the Take 5 customer experience program

- A total of 40 pet owners and 66 veterinarians completed evaluations
- EASOTIC® (hydrocortisone aceponate, miconazole nitrate, gentamicin sulfate) Otic Suspension for Dogs was administered for 5 days in dogs with otitis externa
- Pet owners were surveyed on Days 1, 2, 5, and 14; veterinarians were surveyed on Day 1 and at the recheck appointment between Days 14 and 28
- Pet owners and veterinarians evaluated clinical signs and overall satisfaction with treatment results. Pet owners also evaluated ease of product use; veterinarians evaluated the organisms observed

Percent of pet owners observing signs (n=40)



EASOTIC® (hydrocortisone aceponate, miconazole nitrate, gentamicin sulfate) Otic Suspension for Dogs is contraindicated in dogs with known or suspected hypersensitivity to corticosteroids, imidazole antifungals, or aminoglycoside antibiotics. Not for use in dogs with known tympanic membrane (ear drum) perforation.

## Satisfaction guaranteed with just 1 pump a day for 5 days

Pet owners reported **rapid relief** and **sustained resolution** of signs, along with **high levels of satisfaction** with both ease of administration and treatment results.

**93% OF PET OWNERS** found treatment easy to use.

**90% OF PET OWNERS** were satisfied with the results of treatment.

**88% OF VETERINARIANS** were satisfied with the results of treatment.

### BY TREATMENT DAY 2, IMPROVEMENT WAS OBSERVED

in shaking their head, scratching ears, ear redness, rubbing their head and ears, and having ear discharge.

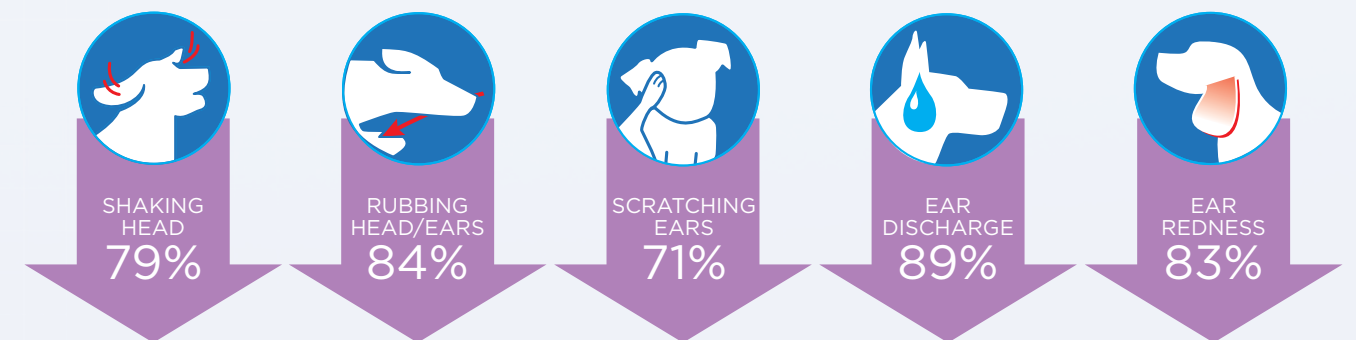
### BY TREATMENT DAY 5, 98% OF PET OWNERS described ear discharge as ABSENT or RARE.

≥85% OF PET OWNERS reported only RARE occurrences of their dog shaking their head, scratching ears, ear redness, rubbing their head and ears, or having ear discharge.

### ON DAY 14 (9 DAYS AFTER THE FINAL TREATMENT), further improvement

in the majority of signs was observed.

## Reductions in number of dogs demonstrating signs between Days 1 and 5



For all clinical signs, pet owners reported sustained results at Day 14

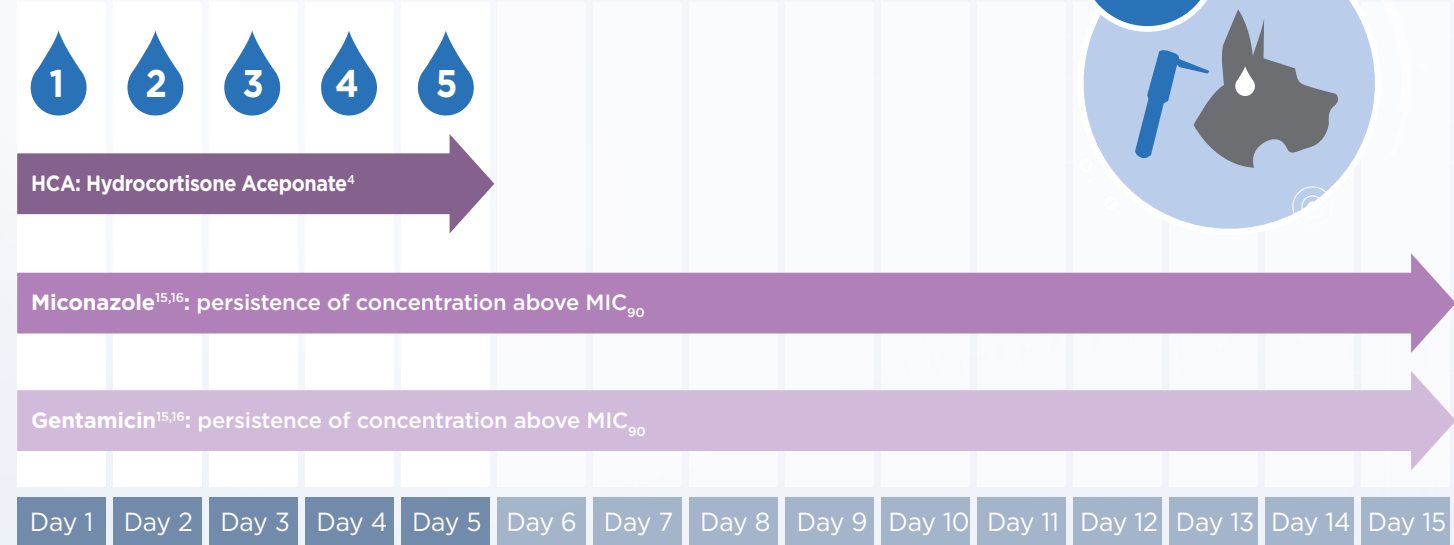
Program overview: Survey data gathered from 40 pet owners and 66 veterinarians. Product was administered once daily for 5 days in dogs with otitis externa. Pet owners provided evaluations on Days 1, 2, 5, and 14; veterinarians, on Day 1 and at the recheck appointment between Days 14 and 28.

**easOtic®**

(hydrocortisone aceponate, miconazole nitrate, gentamicin sulfate)  
Otic Suspension For Dogs

# Duration of activity of ingredients<sup>15,16</sup>

**easOtic**<sup>®</sup>  
(hydrocortisone aceponate, miconazole nitrate, gentamicin sulfate)  
Otic Suspension For Dogs



- Humans with known or suspected hypersensitivity to hydrocortisone, aminoglycoside antibiotics, or azole antifungals should not handle this product
- Contraindicated in dogs with known or suspected hypersensitivity to corticosteroids, imidazole antifungals, or aminoglycoside antibiotics



**References:** 1. Woodward, M. Otitis externa in animals. Merck Veterinary Manual. Available at: <https://www.merckvetmanual.com/ear-disorders/otitis-externa/otitis-externa-in-animals>. Updated October 2020. Accessed July 27, 2021. 2. Bajwa J. Canine otitis externa—Treatment and complications. *Vet Derm.* 2019;60:97-99. 3. Data on file, Virbac Corporation. 4. Guaguere E, Bensignor E, Carlotti DN, et al. Clinical practice guidelines on the best use of topical glucocorticoids in canine dermatology. *Prat Med Chir Anim Comp.* 2011;46:S1-S20. 5. Schackert C, Korting HC, Schafer-Korting M. Qualitative and quantitative assessment of the benefit/risk ratio of medium potency topical corticosteroids in vitro and in vivo. *BioDrugs.* 2000;13(4):267-277. 6. Schafer-Korting M, Gysler A. Topical glucocorticoids with improved benefit/risk ratio. In: Korting HC, Schafer-Korting M, eds. *The Benefit/Risk Ratio: A Handbook for The Rational Use of Potentially Hazardous Drugs.* Boca Raton, FL: CRC Press; 1999:359-372. 7. EASOTIC<sup>®</sup> (hydrocortisone aceponate, miconazole nitrate, gentamicin sulfate) Otic Suspension for Dogs [product label]. Fort Worth, TX: Virbac AH, Inc.; 2020. 8. OTOMAX<sup>®</sup> Ear Drops Suspension (gentamicin sulfate, betamethasone valerate and clotrimazole) [data sheet]. United Kingdom: MSD Animal Health; 2020. 9. Posatex<sup>®</sup> (orbifloxacin, mometasone furoate, posaconazole) Ear Drop Suspension for Dogs [product label]. Madison, NJ: Merck Animal Health; 2019. 10. Posatex<sup>®</sup> (orbifloxacin, mometasone furoate, posaconazole) Ear Drop Suspension for Dogs [summary of product characteristics]. The Netherlands: Intervet International BV; 2013. 11. Mometamax<sup>®</sup> (gentamicin sulfate, mometasone furoate monohydrate, and clotrimazole) Otic Suspension [product label]. Madison, NJ: Merck Animal Health; 2016. 12. CLARO<sup>®</sup> (florfenicol, terbinafine, mometasone furoate) Otic Solution [product label]. Shawnee Mission, KS: Bayer Healthcare LLC; 2018. 13. OSURNIA<sup>®</sup> (florfenicol, terbinafine, betamethasone acetate) [product label]. Greenfield, IN: Elanco US Inc; 2016. 14. Suroilan<sup>®</sup> (miconazole nitrate, polymyxin B sulfate, prednisolone acetate) Otic Suspension [product label]. Greenfield, IN: Elanco; 2018. 15. Rigaut D, Sanquer A, Maynard L, Rème, C. Efficacy of a topical ear formulation with a pump delivery system for the treatment of infectious otitis externa in dogs: a randomized controlled trial. *Intern J Appl Res Vet Med.* 2011;9(1):15-28. 16. Rey-Grobbellet X, Rigaut D, Maynard L, Rème CA. Persistence of antimicrobials in the ear canal of dogs treated once daily for 5 days with 1 ml of a topical ear formulation. *Virbac SA, Carros, F-06511 France;* 2010. 17. Boda C, Liege P, Rème C. Evaluation of owner compliance with topical treatment of acute otitis externa in dogs: a comparative study of two auricular formulations. *Intern J Appl Res Vet Med.* 2011;9(2):157-165.

**easOtic**<sup>®</sup>  
(hydrocortisone aceponate, miconazole nitrate, gentamicin sulfate)  
Otic Suspension For Dogs

# 93% OF PET OWNERS

found treatment easy to use

## Easy to deliver the full dose needed for effective treatment

Features an ergonomically designed applicator that makes administration less frustrating and enhances client compliance<sup>17</sup>

### FLEXIBLE NOZZLE

Gentle, atraumatic nozzle for applying the accurate dose into the ear canal

### EASY DOSING

Just 1 pump in each ear, once a day for 5 days



### TEXTURED GRIP

To avoid finger slipping

### PUMP DELIVERY

The correct dose in a single press

### ERGONOMIC SHAPE

To facilitate easy handling and use

### AIRLESS BOTTLE

Prevents retro contamination and allows accurate dosing at any angle, even upside down



TO ORDER, CONTACT YOUR DISTRIBUTOR OR VIRBAC REPRESENTATIVE, OR CALL 1-844-4-VIRBAC (1-844-484-7222). VISIT US.VIRBAC.COM TO LEARN MORE.

