easOtic®

(hydrocortisone aceponate/
miconazole nitrate/
gentamicin sulfate)

Otic Suspension For Dogs

Effective. Innovative. Easy.

Proven results for the treatment of canine otitis externa,[1–3] harnessing the potency of hydrocortisone aceponate (HCA), the broad-spectrum efficacy of gentamicin,[4] and the consistent results of miconazole.[1,11]

Shaping the future of animal health

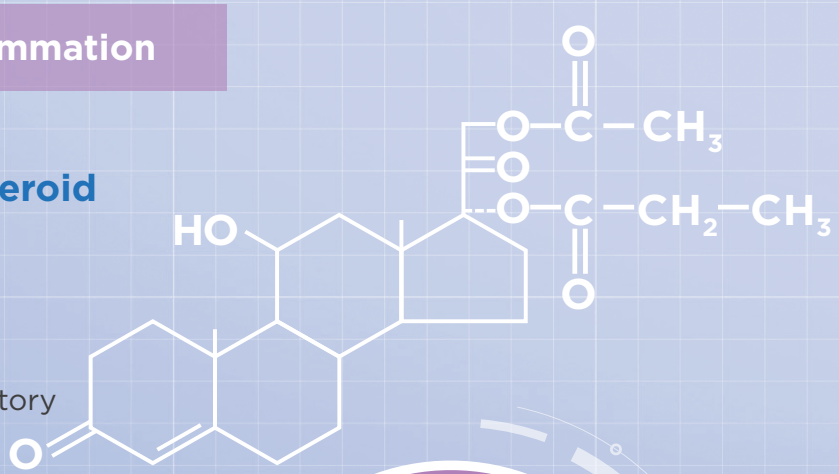
Virbac

Three hard-working ingredients for

1 HCA—effective against local inflammation

HCA is a new generation di-ester steroid with clear advantages:

- Quick and effective dose concentrations are reached in epidermis and dermis[5,15]
- Acts as a pro-drug providing anti-inflammatory action to the targeted tissues[5,12,15]
- HCA plays an anti-inflammatory role in providing results beyond the 5 day treatment protocol[1]



HCA IS A NEW GENERATION STEROID ALLOWING A TREATMENT PROTOCOL OF JUST 5 DAYS[1,2].

HCA is activated and metabolized in the skin, allowing for:

- Higher concentrations in the skin than with conventional treatments[7]
- Potent anti-inflammatory effects with better local and systemic tolerance than conventional treatments[5]

2 Gentamicin—a proven antimicrobial

- Broad-spectrum antimicrobial recommended for first-line use[4,6]
- Excellent safety profile documented in well-controlled studies[8]
- Demonstrated efficacy for treatment of otitis externa caused by 2 commonly diagnosed organisms[9,10]

3 Miconazole—a trusted anti-fungal

- Potent antifungal
- Proven consistent results[1,4,11]

r easy 5-day treatment

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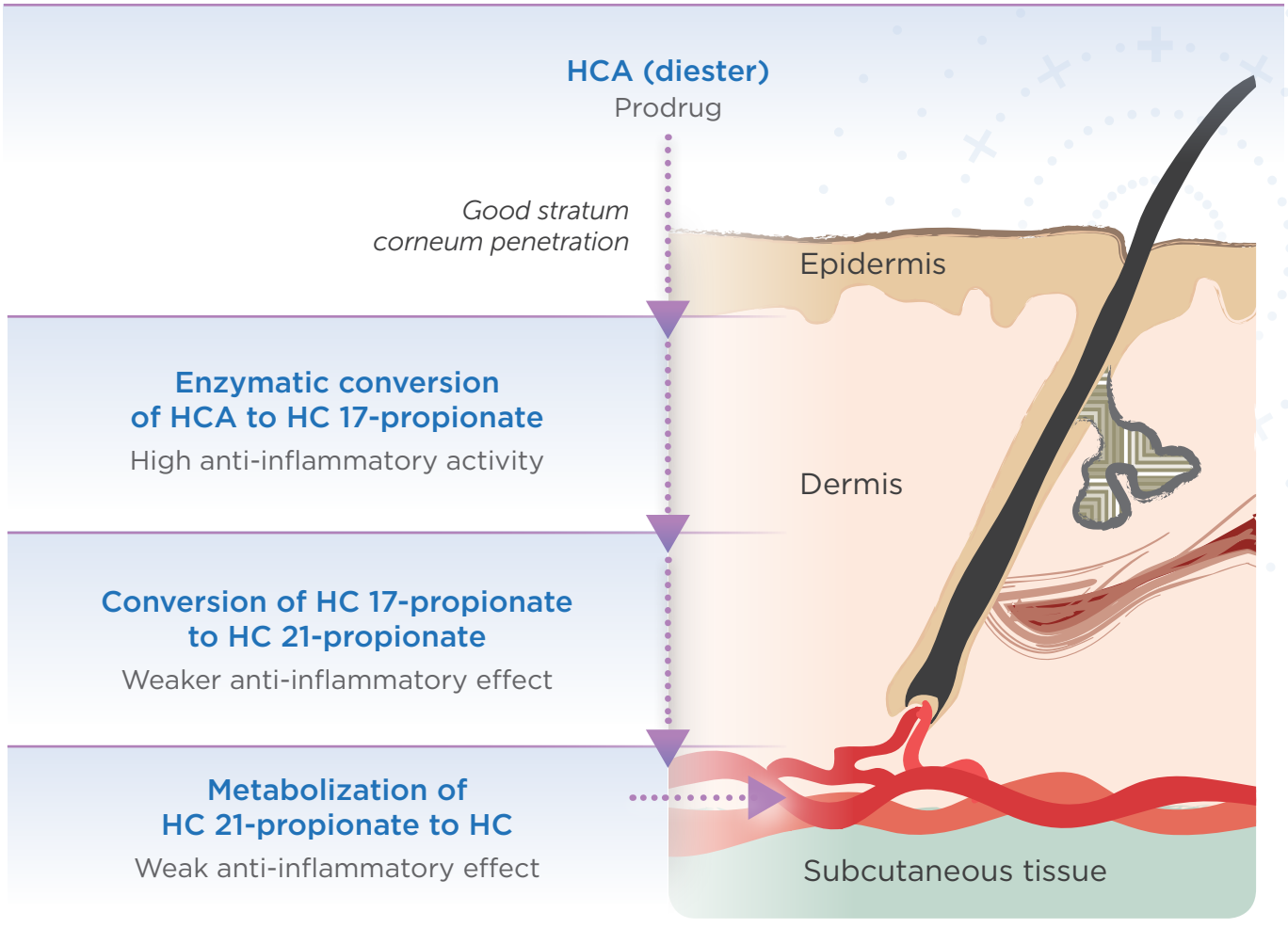
The unique pathway of HCA

Unlike older generation glucocorticoids, the 3-step activation and conversion of HCA occurs in the skin resulting in high local efficacy and a low risk of systemic side effects.[5,7,12]

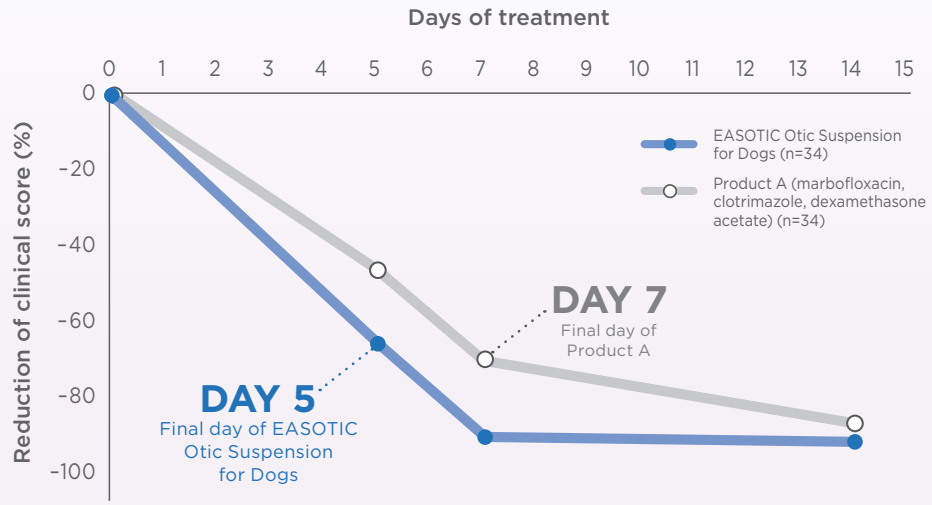


Important Safety Information for EASOTIC® (hydrocortisone aceponate, miconazole nitrate, gentamicin sulfate) Otic Suspension for Dogs: Contraindicated in dogs with known or suspected hypersensitivity to corticosteroids, imidazole antifungals, or aminoglycoside antibiotics. Do not use in dogs with known tympanic membrane (ear drum) perforation. The safe use of EASOTIC Otic Suspension used for breeding purposes, during pregnancy, or in lactating bitches has not been evaluated. For otic (ear) use in dogs only. Do not administer orally. Not for use in humans. Humans with known or suspected hypersensitivity to hydrocortisone, aminoglycoside antibiotics, or azole antifungals should not handle this product. For complete product information, refer to the product insert. To obtain a product insert, contact Veterinary Technical Product Support at 1-800-338-3659, or visit **us.virbac.com**.

Easy-to-see advantages

Just 5 days of EASOTIC® (hydrocortisone aceponate, miconazole nitrate, gentamicin sulfate) Otic Suspension for Dogs is comparable to other 7-day treatments[13]

Aggregate reduction of clinical scores of EASOTIC Otic Suspension for Dogs versus a 7-day treatment[1,13]



Observed pruritus, pain, excoriation, erythema, exudate, stenosis and supuration scores at day 7 for dogs that received treatment with EASOTIC Otic Suspension for Dogs for 5 days were lower than these same scores for dogs that received product A (10 drops a day for 10 days). Follow-up scores (at day 14) were comparable.[13]

A recent study shows EASOTIC Otic Suspension for Dogs is comparable to gel treatment

AFTER 1 WEEK:

- Lower OTIS-3 scores (*P*=0.0027)[14]
- Less pruritus observed (*P*=0.0232)[14]

Overall treatment success was similar for both products.[14]

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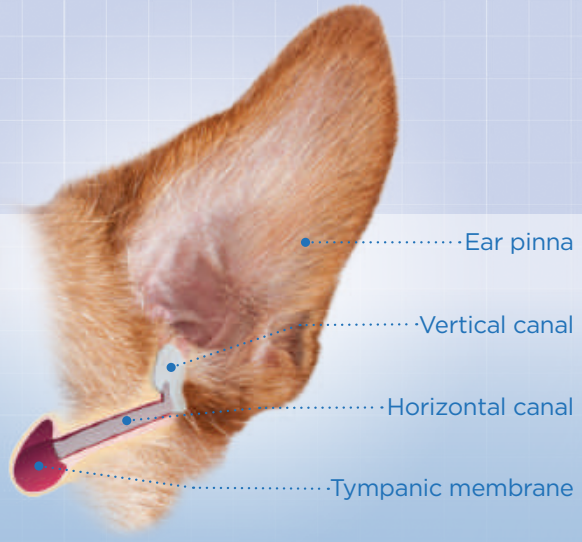
(hydrocortisone aceponate/ miconazole nitrate/ gentamicin sulfate)

Otic Suspension For Dogs



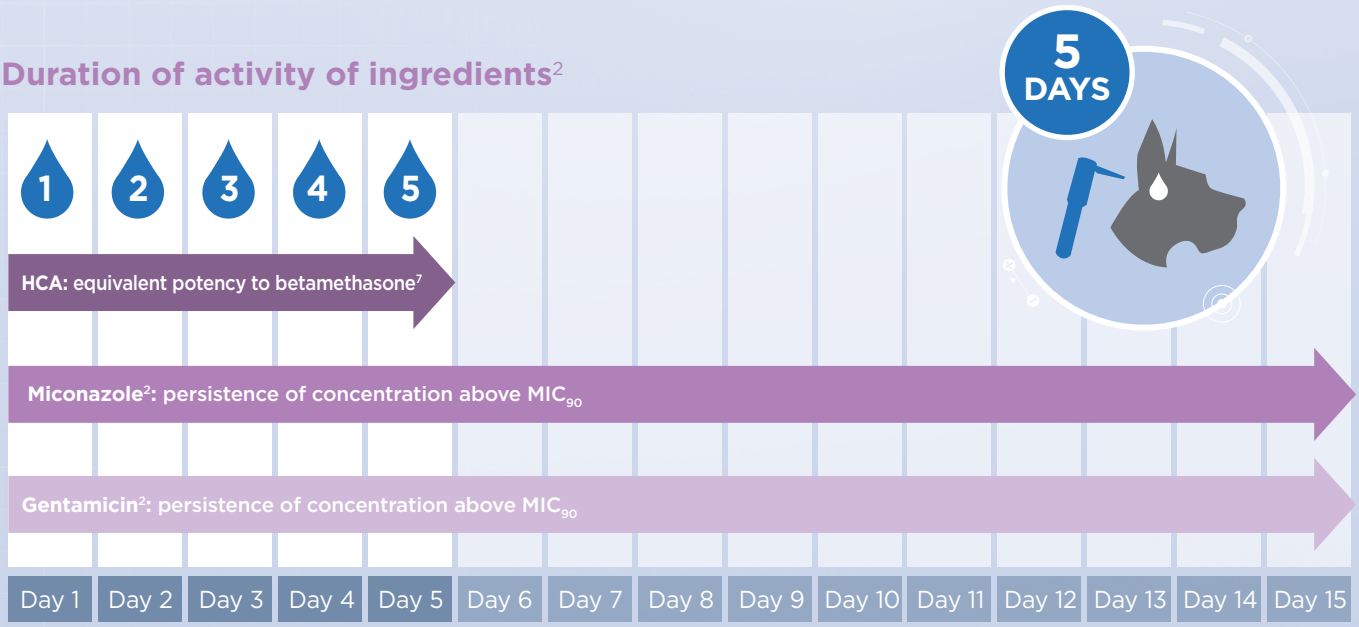
Easy to deliver the full dose needed for effective treatment

- Covers an extended surface area in the ear canal of any size or breed of dog[1,13]
- Reaches the tympanic membrane in medium to large dogs[13]

Just one pump in the ear, once a day for 5 days

Simply use EASOTIC Otic Suspension for Dogs once a day for 5 days to treat the infected ear. Ear cleaning can be performed before and during treatment if necessary[16].

Duration of activity of ingredients[2]



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Easy to administer

Award-winning bottle design* shown to improve owner compliance (*P*=0.0081) with canine otitis externa treatments.[3]

TEXTURED GRIP

To avoid finger slipping

EASY DOSING

One press, once a day for only 5 days per ear

FLEXIBLE NOZZLE

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

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

79%

EASOTIC®
(hydrocortisone aceponate, miconazole nitrate, gentamicin sulfate) Otic Suspension for Dogs

DOG OWNER COMPLIANCE[3]

21%

Surolan®
(miconazole nitrate, polymyxin B sulfate, prednisolone acetate) Otic Suspension

100% owner satisfaction with EASOTIC Otic Suspension for Dogs[3]

- Overall satisfaction
- Duration of treatment
- Frequency of treatment

*2009 Pharmapack award winner.

easOtic®

(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 canister, prime the pump by depressing the pump 1 to 2 times to fill the clear 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, or azole 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 ototoxicty, 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 Supsension.

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 at 800-338-3659 or the FDA at 1-888-FDA-VETS.

For technical assistance or to obtain a Safety Data Sheet, call Virbac at 800-338-3659.

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

NADA 141-330, Approved by FDA.

Revision Date 7/2017

302076-03

Five reasons why the choice is easy

EASOTIC® (hydrocortisone aceponate, miconazole nitrate, gentamicin sulfate) Otic Suspension for Dogs:

1. Delivers potent active ingredients, with low risk of systemic side effects[5,7,15]
2. HCA is a new-generation di-ester steroid having a strongly positive benefit/risk ratio[15]
3. Contains proven antimicrobial and antifungal agents[4,6,10,11]
4. Features an ergonomically designed applicator that makes administration less frustrating and enhances client compliance[13]
5. Shown to provide rapid and sustained treatment of infectious otitis externa with 5 once-daily doses[1–3,13,14]

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.

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References: 1. Rigaut D, Sanquer A, Maynard L, Reme CA. 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. **2.** Rey-Grobellet 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. **3.** Boda C, Liege P, Reme 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. **4.** Lyskova P, Vydrzalova M, Mazurova J. Identification and antimicrobial susceptibility of bacteria and yeasts isolated from healthy dogs and dogs with otitis externa. *J Vet Med*. 2007;A54:559–563. **5.** Schackert C, Korting HC, Schäfer-Körting 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.** Hariharan,Harry, McPhee, Lynn, Heaney,Susan, Bryenton, James; Antimicrobial drug susceptibility of clinical isolates of Pseudomanas aeruginosa. Can Vet J 1995; 36:166-168 **7.** 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. **8.** Strain GM, Merchant SR, Neer TM, Tedford BL. Ototoxity assessment of a gentamicin sulfate otic preparation in dogs. *Am J Vet Res*. 1995;56:532–538. **9.** Schick AE, Angus JC, Coyner KS. Variability of laboratory identification and antibiotic susceptibility reporting of *Pseudomonas* spp. isolates from dogs with chronic otitis externa. *Vet Dermatol*. 2007;18:120–126. **10.** Seol B, Naglic T, Madic J, Bedekovic M. In vitro antimicrobial susceptibility of 183 *Pseudomonas aeruginosa* strains isolated from dogs to selected antipseudomonal agents. *J Vet Med*. 2002;49(4):188–192. **11.** Barasch,Andrei, Griffin, Andreea Voinea. Miconazole revisited: new evidence of antifungal efficacy from laboratory and clinical trials **12.** Mori M, Pimpenelli N, Gannott B. Topical corticoids and unwanted local effects, improving the benefit/risk ratio. *Drug Safety*. 1994;10:406–412. **13.** Rigaut- EASOTIC Dose Titration v. Aurizon Poster ESVD 2009 Dose titration Easotic. **14.** King SB, Doucette KP, Seewald W, Forster SL. A randomized, controlled, single-blinded, multicenter evaluation of the efficacy and safety of a once weekly two dose otic gel containing florfenicol, terbinafine and betamethasone administered for the treatment of canine otitis externa. *BMC Vet Res*. 2018;14:307. **15.** Schäfer-Körting M, Gysler A. Topical glucocorticoids with improved benefit/risk ratio. In: Korting HC, Schäfer-Körting M, eds. *The Benefit/Risk Ratio: A Handbook for The Rational Use of Potentially Hazardous Drugs*. Boca Raton, FL: CRC Press; 1999:359–372. **16.** Navarro_Easotic & Epiotic in the ear canal_ESVD proceedings 2014.

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