Ease and otic together at last.

A unique, new-generation steroid makes otitis externa simpler to treat.
Dogs suffering from acute episodes of otitis externa can experience moderate to high recurrence because of underlying seasonal or perennial allergies. The primary areas affected by this type of otitis externa are:

• The proximal pinna
• The vertical and horizontal ear canal

SIMPLIFY TREATMENT for many of your patients.

HCA is 60 times more lipophilic than hydrocortisone (HC), resulting in:

- Quick and effective dose concentrations reached in epidermis and dermis\(^2,3\)
- Persistence in target tissue that extends the therapeutic effect beyond the 5-day dosing duration\(^4\)

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

- Higher concentrations in the skin than with conventional treatments\(^4\)
- Potent anti-inflammatory effects with better local and systemic tolerance than conventional treatments\(^2\)

EASy 5-DAY TREATMENT (hydrocortisone aceponate, miconazole nitrate, gentamicin sulfate)

The unique characteristics of this new-generation steroid are the key to shorter treatment regimens.

\(^1\) HCA is activated and metabolized in the skin, allowing for:

- Quick and effective dose concentrations reached in epidermis and dermis\(^2,3\)
- Persistence in target tissue that extends the therapeutic effect beyond the 5-day dosing duration\(^4\)

- Higher concentrations in the skin than with conventional treatments\(^4\)
- Potent anti-inflammatory effects with better local and systemic tolerance than conventional treatments\(^2\)
Unlike older-generation glucocorticoids, the metabolism of HCA occurs in the skin and exhibits high local efficacy and a low risk of systemic side effects.¹⁵

**Clinical Signs to Look For**

- Rubbing the head or ears on furniture or the floor
- Scratching at the ears
- Shaking the head
- Redness of the ear canal and pinna
- An aural hematoma
- Pain in the ear or, rarely, aggression when the head is approached

**Easy 5-Day Treatment**

powered by hydrocortisone aceponate (HCA).
Efficacy of EASOTIC® (hydrocortisone aceponate, miconazole nitrate, gentamicin sulfate) Otic Suspension for Dogs is comparable to 7-day treatments, in less time and with less hassle.\(^6\)

Aggregate reduction of clinical scores of EASOTIC Otic Suspension for Dogs vs. a 7-day treatment\(^6\)

1 mL of EASOTIC Otic Suspension for Dogs per day for 5 days had lower clinical score measurements for pruritus, pain, excoriation, erythema, exudate, stenosis, and suppuration than Product A (10 drops per day for 7 days) and was comparable at follow-up on Day 14.\(^6\)
E ADVANTAGES of a simpler, 5-day treatment regimen.

Easy to deliver the full 1-mL dose needed for effective treatment.

- Covers an extended surface area in the ear canal of any size or breed of dog\(^4,6\)
- Reaches the tympanic membrane in medium to large dogs\(^6\)

Providing a 1-mL dose is not as easy with conventional treatments.

\[\text{ONE PUMP} = \text{UP TO 40 DROPS}\]

Provides the 3-way action needed to treat otitis externa.

- **Anti-inflammatory** (hydrocortisone aceponate)
- **Antifungal** (miconazole nitrate)
- **Antimicrobial** (gentamicin sulfate)

*Ease and otic together at last.*
Innovation that makes treatment easier for your clients.

- Conventional drops and ointments can make dosing difficult and hinder client compliance
- EASOTIC Otic Suspension for Dogs is designed to enhance compliance and help improve outcomes

EASY TO ADMINISTER
thanks to an award-winning design that boosts compliance.*

FLEXIBLE NOZZLE
is gentle on sensitive canine ears.

CONVENIENT APPLICATOR
allows administration in any position.

AIRLESS DELIVERY SYSTEM
enables an exact 1-mL dose every time with a single pump.

Innovation that makes treatment easier for your clients.

- Conventional drops and ointments can make dosing difficult and hinder client compliance
- EASOTIC Otic Suspension for Dogs is designed to enhance compliance and help improve outcomes

* 2009 Pharmapack award winner.

79%
DOG OWNERS COMPLIANT

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

21%
DOG OWNERS COMPLIANT

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

100% OWNER SATISFACTION with EASOTIC Otic Suspension for Dogs

- Overall satisfaction
- Duration of treatment
- Frequency of treatment
EASOTIC®
Otic suspension (hydrocortisone aceponate, miconazole nitrate, gentamicin sulfate)
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® suspension contains 1.11 mg/mL hydrocortisone aceponate, 15.1 mg/mL miconazole nitrate and 1.5 mg/mL gentamicin sulfate. The inactive ingredient is a semi-liquid petroleum jelly.

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

DOSE 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 suspension once per day for 5 days. Wash hands after usage.

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

EASOTIC® 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 ototoxicity, vestibular dysfunction and renal toxicity. The use of EASOTIC® 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® 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® 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® 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 at 800-338-3659 or the FDA at 1-888-FDA-VETS.

For technical assistance or to obtain a material 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® 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® 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® 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® 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® 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® 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 20º C-25º C (68º F-77º F), with excursions permitted between 15º C-30º C (59º F-86º F).

HOW SUPPLIED: EASOTIC® 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.
Fort Worth, TX 76137 USA
NADA 141-330, Approved by FDA.
Revision Date 8/2011
302076-01

EasOtic
Otic Suspension For Dogs
Ease and otic together at last.
5 REASONS
THE CHOICE IS EASY
for otitis externa treatment.

EASOTIC Otic Suspension for Dogs:

1. Contains HCA, a new-generation steroid that enables simple, 5-day treatment regimens.
2. Delivers potency of conventional topical treatments with low risk of systemic side effects.
3. Delivers an exact 1-mL dose with a single pump.
4. Contains proven antimicrobial and antifungal agents.
5. Features an ergonomically designed applicator that makes administration less frustrating and enhances client compliance.

Replace the hassle of treatment with 5 days of easy.

Talk to your Virbac representative, visit www.virbacvet.com, or call 1-800-338-3659.

Important safety information: EASOTIC Otic Suspension for Dogs is contraindicated in dogs with known or suspected hypersensitivity to corticosteroids, imidazole antifungals, or aminoglycoside antibiotics. Do not use in dogs with known tympanic membrane perforation. The safe use of EASOTIC Otic Suspension for Dogs in dogs used for breeding purposes, during pregnancy, or in lactating bitches has not been evaluated. See package insert for additional product information.

References:

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