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*).

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 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.

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Virbac ANIMAL HEALTH

Passionate About Animal Health