DOG OWNER
ADMINISTRATION SHEET

Your veterinarian has prescribed EASOTIC® (hydrocortisone aceponate, miconazole nitrate, gentamicin sulfate) Otic Suspension for Dogs. Before you begin treatment, please review the following instructions to help ensure proper administration.

**Step 1**
Shake the canister vigorously for at least 30 seconds. The ball bearings inside the canister help ensure the contents are thoroughly mixed.

**Step 2**
Remove the clear cap before use. **If the canister has not been primed, then press firmly on the pump several times until product fills the nozzle.** This should only be needed prior to the first use.

**Step 3**
Insert the nozzle into your dog’s ear canal and firmly press down on the pump 1 time to deliver the full 1-mL dose.*

It may help to massage the medication into your dog’s ear. Wipe the nozzle clear of debris, replace the cap, and store upright.

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**Important Safety Information**

**EASOTIC® (hydrocortisone aceponate, miconazole nitrate, gentamicin sulfate) Otic Suspension for Dogs: For otic (ear) use in dogs only.** 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 in dogs used for breeding purposes has not been evaluated. Do not administer orally. Humans with known or suspected hypersensitivity to hydrocortisone, aminoglycoside antibiotics, or azole antifungals should not handle this product. For complete information or to obtain a package insert, contact Virbac at 1-800-338-3659, or visit us.virbac.com.

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*Follow your veterinarian’s instructions regarding dosing.

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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); 66.5% 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.
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