



Osurnia®

(florfenicol, terbinafine, betamethasone acetate)

Otic gel

For Otic Use in Dogs Only

Do not use in cats

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

BRIEF SUMMARY (for full prescribing information, see package insert)

DESCRIPTION: OSURNIA contains 10 mg florfenicol, 10 mg terbinafine and 1 mg betamethasone acetate per mL and the inactive ingredients: propylene carbonate, glycerol formal, hypromellose, phospholipid, oleic acid and BHT in an off-white to slightly yellow translucent gel.

INDICATION: OSURNIA is indicated for the treatment of otitis externa in dogs associated with susceptible strains of bacteria (*Staphylococcus pseudintermedius*) and yeast (*Malassezia pachydermatis*).

DOSE AND ADMINISTRATION: OSURNIA should be administered in the clinic. Clean and dry the external ear canal before administering the initial dose of the product. Administer one dose (1 tube) per affected ear(s) and repeat administration in 7 days. Do not clean the ear canal for 45 days after the initial administration to allow contact of the gel with the ear canal. Cleaning the ear may affect product effectiveness (see **Effectiveness** in the product insert). If alternative otic therapies are required it is recommended to clean the ear(s) before application. Open tube by twisting the soft tip. Insert the flexible tip into the affected external ear canal(s) and squeeze entire tube contents into the external ear canal(s). After application, gently massage the base of the ear to allow the gel to penetrate to the lower part of the ear canal.

CONTRAINDICATIONS: Do not use in dogs with known tympanic perforation (see **Precautions** in the product insert). Do not use in dogs with a hypersensitivity to florfenicol, terbinafine, or corticosteroids.

WARNINGS:

Human Safety Warning:

OSURNIA may cause eye injury and irritation

Not for use in humans. Keep this and all medications out of reach of children. Consult a physician in case of accidental ingestion by humans. In case of accidental skin contact, wash area thoroughly with water. Avoid contact to the eyes. In case of accidental eye contact, flush thoroughly with water for at least 15 minutes. If symptoms develop, seek medical advice.

PRECAUTIONS: Wear eye protection when administering OSURNIA and restrain the dog to minimize post-application head shaking. Reducing the potential for splatter of product will help prevent accidental eye exposure in people and dogs and help to prevent ocular injury. Do not administer orally. The use of OSURNIA in dogs with perforated tympanic membranes has not been evaluated. The integrity of the tympanic membrane should be confirmed before administering this product. Reevaluate the dog if hearing loss or signs of vestibular dysfunction are observed during treatment. Use of topical otic corticosteroids has been associated with adrenocortical suppression and iatrogenic hyperadrenocorticism in dogs (see **Animal Safety** in the product insert). Use with caution in dogs with impaired hepatic function (see **Animal Safety** and **Adverse Reactions** in the product insert). The safe use of OSURNIA in dogs used for breeding purposes, during pregnancy, or in lactating bitches, has not been evaluated.

ADVERSE REACTIONS: The following adverse reactions were reported during the course of a US field study for treatment of otitis externa in dogs treated with OSURNIA in decreasing order: elevated liver enzymes, vomiting, weight loss (>10% body weight) and hearing loss. To report suspected adverse events, for technical assistance or to obtain a copy of the SDS, contact Dechra Veterinary Products at (866) 933-2472. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at <http://www.fda.gov/AnimalVeterinary/SafetyHealth>.

POST-APPROVAL EXPERIENCE (2020): The following adverse events are based on post-approval adverse drug experience reporting for OSURNIA. Not all adverse events are reported to FDA/CVM. It is not always possible to reliably estimate the adverse event frequency or establish a causal relationship to product exposure using this data.

In humans, accidental exposure leading to corneal ulcers and other ocular injuries such as eye irritation, burning, stinging, and itchiness have been reported to occur when the dog shook its head after application of OSURNIA.

In dogs, the adverse events reported for OSURNIA are presented below in decreasing order of reporting frequency: Deafness, ear discharge, ear irritation and pain, vomiting, head shaking, head tilt, ataxia, vocalization, corneal ulcer, keratoconjunctivitis sicca, nystagmus, tympanic rupture, and facial paralysis.

INFORMATION FOR DOG OWNERS: Owners should be aware that adverse reactions may occur following administration of OSURNIA and should observe dog for signs such as deafness, ear pain and irritation, vomiting, head shaking, head tilt, incoordination, eye pain and ocular discharge (see **Animal Safety** and **Post-Approval Experience** in the product insert). Owners should be advised to contact their veterinarian if any of the above signs are observed. Owners should also be informed that splatter may occur if the dog shakes its head following administration of OSURNIA which may lead to ocular exposure. As a result, eye injuries in humans and dogs have been reported including corneal ulcers.

EFFECTIVENESS: Effectiveness was evaluated in 235 dogs with otitis externa. The study was a double-masked field study with a placebo control (vehicle without the active ingredients). One hundred and fifty-nine dogs were treated with OSURNIA and seventy-six dogs were treated with the placebo control. All dogs were evaluated for safety. Treatment (1 mL) was administered to the affected ear(s) and repeated 7 days later. Prior to the first administration, the ear(s) were cleaned with saline but not prior to the Day 7 administration. Six clinical signs associated with otitis externa were evaluated: pain, erythema, exudate, swelling, odor and ulceration. Total clinical scores were assigned for a dog based on the severity of each clinical sign on Days 0, 7, 14, 30 and 45. Success was determined by clinical improvement at Day 45. The success rates of the two groups were significantly different ($p=0.0094$); 64.78% of dogs administered OSURNIA were successfully treated, compared to 43.42% of the dogs in the placebo control group.

STORAGE CONDITIONS: OSURNIA should be stored under refrigerated conditions between 36° - 46° F (2° - 8° C). To facilitate comfort during administration, OSURNIA may be brought to room temperature and stored for up to three months.

MANUFACTURED FOR:

Dechra Veterinary Products
7015 College Boulevard, Suite 525
Overland Park, KS 66211 USA
Product of Great Britain

Approved by FDA under NADA # 141-437

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