# Recheck for relief done right.

**Canine otitis externa (OE) treatment is only successful when you're confident your treatment is working.**

That's why the follow-up appointment is so important. Resolve the infection with 2-dose Osurnia® (florfenicol-terbinafine-betamethasone acetate), use the follow-up to monitor the response to treatment and trust the Dechra dermatology portfolio to help you treat the underlying problem.

**Because when it comes to treating canine OE, a "one-and-done" treatment leaves many questions unanswered.**

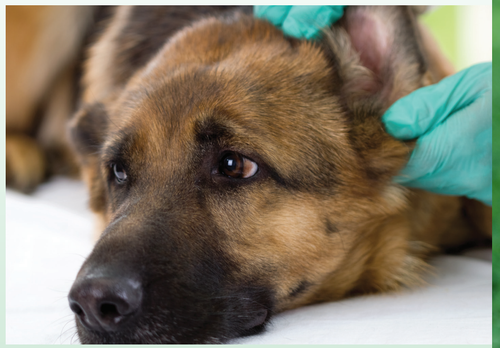
- *Was the underlying issue identified?*
- *Is the ear infection actually improving?*
- *Is the ear infection likely to return?*
- *Are more diagnostics warranted?*

**The follow-up appointment isn't a "nice-to-have." It's necessary to get to the root of the problem.**

With two doses delivered by you, Osurnia delivers results.

# We're here for ears.

## The Dechra portfolio can help you solve even the most stubborn OE cases.



Chronic or recurrent canine OE is a common problem for patients. Osurnia® (florfenicol, terbinafine, betamethasone acetate) will resolve the infection. But if an underlying condition is to blame, OE will present itself again in the future. This creates a painful cycle for patients and frustration for clients.

The Dechra dermatology portfolio specializes in solutions for skin and ear health—including the most common underlying conditions responsible for recurrent canine OE.

## Partner with Dechra for your dermatology needs.

To order or schedule a lunch and learn,
call your Dechra representative or call **(866) 683-0660**.
For more information, please visit ***www.dechra-us.com***.

**Important Safety Information**

As with all drugs, side effects may occur. In field studies and post-approval experience the most common side effects reported were vomiting, increased liver enzymes and loss of hearing. Other signs reported were ear discharge, ear irritation and pain, vomiting, head shaking, head tilt, ataxia, vocalization, corneal ulcer, keratoconjunctivitis sicca, nystagmus, tympanic rupture, and facial paralysis.

Osurnia® should be administered by a veterinary professional. Do not use in dogs with known tympanic perforation or a hypersensitivity to florfenicol, terbinafine or corticosteroids. **Osurnia may cause eye injury and irritation. Wear eye protection when administering Osurnia and restrain the dog** to minimize post-application head shaking. **Do not use in cats.** Refer to the prescribing information for complete details or visit www.dechra-us.com.

Dechra
Veterinary Products

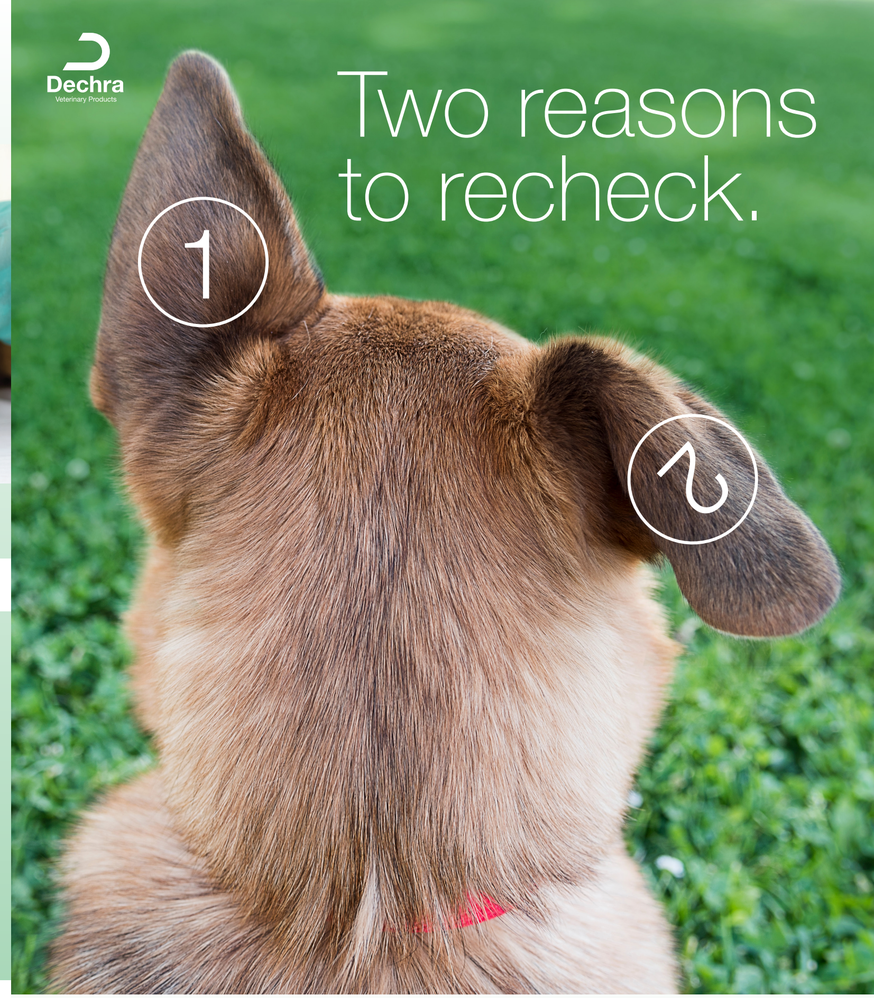
For Veterinary Technical Support Contact Dechra Veterinary Products at:
866-933-2472, www.dechra-us.com, support@dechra.com.



06SD-OSU21012-0421

Dechra
Veterinary Products

# Two reasons to recheck.




Osurnia®
(florfenicol, terbinafine, betamethasone acetate)

Confidently treat canine otitis externa with two-dose Osurnia, part of the Dechra dermatology portfolio.

# All the more reason(s) to reach for Osurnia®

(florfenicol, terbinafine, betamethasone acetate).


**Osurnia offers unique advantages for veterinarians and patients.**

## Applied by You

Each dose is administered by your team with no need to clean the affected ears throughout the course of treatment (45 days)—offering improved compliance and no homework for clients.

## Alcohol-Free Patented Gel

Adaptable gel penetrates deep, coating and adhering to the entire ear canal. Lipophilic formulation works well in a waxy environment.

## Flexible Tip

Soft applicator tip is ideal for thorough administration deep into the ear canal and more comfortable for patients in pain.

## 45-Day Continual Treatment

Patented formulation is uniquely designed to increase contact time at the infection site for long-lasting efficacy and better patient outcomes.

## Easy Administration

Dosing is always accurate. Premeasured, single-dose tube is ready to treat patients of any size without the need to count drops during application.

## Complements the Dechra Portfolio

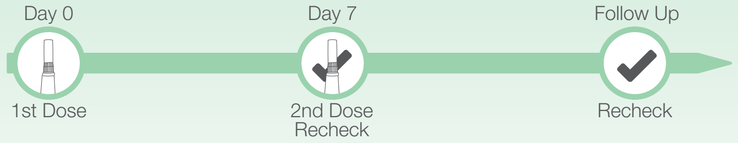
If cytology findings and clinical signs direct you to an underlying problem causing recurrent OE, the Dechra dermatology portfolio can provide solutions.



# Osurnia® (florfenicol, terbinafine, betamethasone acetate) brings the owner back to your clinic.

Successful management of otitis externa (OE) can often involve long-term, or even lifelong, treatment depending on the underlying cause. This care requires a high level of owner commitment and a good relationship between you and your patient's owner.

The benefits of the second dose are twofold. It provides you with an opportunity to recheck the dog mid-treatment to ensure it's responding as planned. It also brings the owner back to the clinic to help build trust and strengthen the relationship while uncovering any necessary next steps to address OE and its underlying cause.




Dechra has a range of products to support you in the treatment and long-term management of OE. The Dechra dermatology portfolio is able to offer you effective, convenient treatment with considerations for your clinical preference and the owner's lifestyle.

**Confidently manage even the most challenging canine OE cases with Osurnia and the Dechra dermatology portfolio.**

# Osurnia®

## (florfenicol, terbinafine, betamethasone acetate)

**Otic Gel**
Antibacterial, antifungal, anti-inflammatory

**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.

**DESCRIPTION:**
OSURNIA contains 10 mg florfenicol, 10 mg terbinafine and 1 mg betamethasone acetate per mL and the inactive ingredients propylene carbonate, glyceryl 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*).

**DOSAGE AND ADMINISTRATION:**
**OSURNIA should be administered by a veterinary professional. Wear eye protection when administering Osurnia** (see **Human Safety Warnings, Precautions, Post-Approval Experience** and **Animal Safety).**

Splatter may occur if the dog shakes its head following administration. Persons near the dog during administration should also take steps to avoid ocular exposure.

1. Clean and dry the external ear canal before administering the initial dose of the product.
2. **Verify the tympanic membrane is intact prior to each administration** (see **Precautions, Contraindications, Animal Safety** and **Post-Approval Experience).**
3. Administer one dose (1 tube) per affected ear(s) and repeat administration in 7 days.
4. Open tube by twisting the soft tip. Insert the flexible tip in 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 the lower part of the ear canal.
5. **Restrain dog to minimize post-application head shaking** to reduce potential for splatter of product, and accidental eye exposure in people and dogs (see **Post-Approval Experience and Animal Safety**).
6. 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**). If alternative otic therapies are required, it is recommended to clean the ear(s) before application.

**CONTRAINDICATIONS:**
Do not use in dogs with known tympanic perforation (see **Precautions**).

Do not use in dogs with a hypersensitivity to florfenicol, terbinafine or corticosteroids.

**WARNINGS:**
**Human Safety Warnings:**

**OSURNIA may cause eye injury and irritation** (see **Precautions, Post-Approval Experience** and **Animal Safety).**

In case of accidental eye contact, flush thoroughly with water for at least 15 minutes. If symptoms develop, seek medical advice.

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.

**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 (see **Human Safety Warnings, Post-Approval Experience** and **Animal Safety**).

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.

Proper patient selection is important when considering the benefits and risks of using OSURNIA. The integrity of the tympanic membrane should be confirmed before administering each dose of product.

Changes to the middle ear, such as ulceration of the mucosal lining, have been associated with OSURNIA administration. (see **Animal Safety**).

Signs of tympanic membrane rupture, internal ear disease such as head tilt, ataxia, nystagmus, facial paralysis, and keratoconjunctivitis sicca have also been reported (see **Post-Approval Experience**).

Do not administer orally.

Use of topical otic corticosteroids has been associated with adrenocortical suppression and iatrogenic hyperadrenocorticism in dogs (see **Animal Safety**).

Use with caution in dogs with impaired hepatic function (see **Animal Safety** and **Adverse Reactions**).

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 with 1 tube per affected ear(s) and repeated after 7 days:

Frequency of Adverse Reaction by Treatment

| Adverse Reaction | OSURNIA (n=190) | Placebo (n=94) |
|---|---|---|
| Elevated Alkaline Phosphatase | 15 (7.9%) | 3 (3.2%) |
| Vomiting | 7 (3.7%) | 1 (1.1%) |
| Elevated AST, ALT, ALP* | 2 (1.1%) | 0 (0.0%) |
| Weight loss (>10% body weight) | 1 (0.53%) | 0 (0.0%) |
| Hearing Decrease/Loss | 1 (0.53%) | 1 (1.1%) |

*Aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase (ALP). Two dogs with pre-existing elevations in ALP were reported to have an increase in liver enzymes (ALP, ALT and/or AST) at study exit. Subsequent clinical chemistries returned to pre-treatment levels in one dog, while no follow-up was performed for the second dog.

**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, pinnal irritation and ear pain, emesis, head shaking, internal ear disorder (head tilt and vestibular), ataxia, vocalization, corneal ulcer, keratoconjunctivitis sicca, nystagmus, tympanic rupture, and cranial nerve disorder (facial paralysis).

OSURNIA is not approved for use in **cats**. The adverse events reported following extra-label use in **cats** are presented below in decreasing order of reporting frequency:

Ataxia, anorexia, Horner's syndrome (third eyelid prolapse and miosis), internal ear disorder (head tilt and vestibular), anisocoria, lethargy, head shake, emesis, nystagmus, deafness, and tympanic rupture.

**CONTACT INFORMATION:**
To report suspected adverse drug events and/or obtain a copy of the Safety Data Sheet (SDS) or for technical assistance, contact Dechra at 1-866-933-2472

For additional information about adverse drug experience reporting for animal drugs, contact the FDA at 1-888-FDA-VETS or www.fda.gov/reportanimalae.

**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**). 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. Owners should be careful to avoid ocular exposure (see **Precautions** and **Post-Approval Experience**).

**CLINICAL PHARMACOLOGY:**
OSURNIA is a fixed combination of three active substances: florfenicol (antibacterial), terbinafine (antifungal) and betamethasone acetate (steroidal anti-inflammatory). Florfenicol is a bacteriostatic antibiotic which acts by inhibiting protein synthesis. Its spectrum of activity includes Gram-positive and Gram-negative bacteria. Terbinafine is an antifungal which selectively inhibits the early synthesis of ergosterol. Betamethasone acetate is a glucocorticosteroid with anti-inflammatory activity.

OSURNIA dissolves in ear wax and is slowly eliminated from the ear mechanically. Ear inflammation can increase the percutaneous absorption of active substances in OSURNIA.

In a laboratory study conducted in healthy dogs (see **Animal Safety**), low plasma concentrations of florfenicol, terbinafine, and betamethasone acetate were measurable during the first 2-4 days after administration of 1X dose, and during the first 2-7 days after administration of 5X dose. No quantifiable plasma concentrations of any of the three active ingredients were observed in the pre-dose samples of most dogs prior to second and third administrations. Although total and peak exposure in the blood tended to be highly variable between dogs, systemic drug concentrations tended to increase in a less than dose-proportional manner as the administered dose increased from 1X to 5X.

**MICROBIOLOGY:**
The compatibility and additive effect of each of the components in OSURNIA 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 determined that florfenicol and terbinafine 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 betamethasone acetate 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 with OSURNIA was met for *Staphylococcus pseudintermedius*, *Malassezia pachydermatis*, and *Pseudomonas aeruginosa*. However, there were only three dogs where *P. aeruginosa* was the only pathogen cultured and they were all treatment failures. Therefore, OSURNIA may not be effective in treating otitis externa in which *P. aeruginosa* is the only pathogen present.

**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.

**ANIMAL SAFETY:**
In a target animal safety study, 24 mixed breed dogs (4 dogs/sex/group) were aurally administered 0X, 1X (1 mL/ear or 2 mL/dog with repeated administration in 7 days) or 5X (5 mL/ear or 10 mL/dog with repeated administration in 7 days) doses of OSURNIA for a total of 6 administrations in 5 weeks. All dogs remained in good health with normal hearing throughout the study. Decreased weight gain was noted in the 1X and 5X groups compared to the control group. Clinical findings included post-administration ear wetness in 1X and 5X groups and unilateral, transient brown/red discharge from one ear each in two 5X dogs, with erythema in one dog after the 4th application. Local microscopic changes in ears (without clinical effects) included: slight or moderate unilateral vesicle formation within the epithelium of the tympanic membrane in two 1X and four 5X dogs, and unilateral mucosal ulceration in the lining of the middle ear cavity in three 5X dogs. Three 5X dogs had slightly elevated ALT activity, accompanied by minimal or mild microscopic hepatocellular vacuolation (in two dogs). Cortisol response to ACTH stimulation was decreased, but within the normal reference range, in 1X dogs. The 5X dogs had a decrease in serum cortisol levels after ACTH stimulation (below normal reference range) accompanied by decreased adrenal gland and thymic weights with minimal adrenal cortical atrophy and slight (in three dogs) or moderate (in one dog also noted with slightly lower lymphocyte counts) lymphoid depletion of the thymus. The ACTH stimulation test results are consistent with systemic absorption of betamethasone resulting in a likely reversible suppression of the hypothalamic-pituitary-adrenal axis as seen with administration of exogenous corticosteroids.

**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.

**HOW SUPPLIED:**
OSURNIA is a gel in a single-use tube with a flexible soft tip, supplied in cartons containing 2 or 20 tubes.

Osurnia 2 tube carton NDC 17033-283-02
Osurnia 20 tube carton NDC 17033-283-20

Approved by FDA under NADA # 141-437

**MANUFACTURED FOR:**
Dechra Veterinary Products
7015 College Boulevard, Suite 525
Overland Park, KS 66211 USA

Product of Great Britain


Rev. December 2020 PIL-44029-002


Dechra