DuOtic
(terbinafine and betamethasone acetate otic gel)

Why treat with more than you need?

Feature #1
Antibiotic-free formula

Its Benefit:
Allows you to practice good antimicrobial stewardship

Feature #2
DuOtic® delivers 45 days of inflammation/infection treatment

Its Benefit:
Provides an extended treatment duration

Feature #3
Two doses, applied in your clinic

Its Benefit:
Ensure the patient receives recommended care

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

Important Safety Information
As with all drugs, side effects may occur. For Otic Use in Dogs Only. **Do not use in cats. Do not use in dogs with known tympanic perforation.** Do not use in dogs with a hypersensitivity to terbinafine or corticosteroids. Do not administer orally. Use with caution in dogs with impaired hepatic function. In a field study and post-approval experience following the use of a similar product Osurnia® (florfenicol, terbinafine, betamethasone acetate) the most common adverse reactions were elevated alanine aminotransferase, conjunctivitis, ocular discharge, ear pruritus, 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).

soundbyte

Dechra
Veterinary Products

DuOtic® is indicated for the treatment of otitis externa in dogs, associated with susceptible strains of yeast (*Malassezia pachydermatis*).

Important Safety Information
The safe use of DuOtic® has not been evaluated in dogs that are pregnant, lactating or intended for breeding. **DuOtic® may cause eye injury and irritation. DuOtic® should be administered by a veterinary professional. Wear eye protection when administering DuOtic® and restrain the dog** to minimize post-application head shaking. Refer to the prescribing information for complete details or visit www.dechra-us.com.

sound byte

CHECK-OFF & ECHO NOTES

State the Issue

Ms. Jones, my exam revealed that Spot has an ear infection caused by yeast.

Or, for a follow-up visit,
Ms. Jones, my exam revealed a need to modify Spot's treatment plan for yeast otitis externa.

State the Solution

I'm changing the treatment to DuOtic® which has ingredients that help relieve inflammation and treat the yeast infection without any antibiotics. I will apply the first dose today and have you bring Spot back for the second dose in 7 days.

Make Your Recommendation

Ms. Jones, I believe DuOtic will be an important tool for managing yeast otitis externa for Spot, especially because I don't see many bacteria on cytology. Do you have any questions?

DuOtic™
(terbinafine and betamethasone acetate otic gel)

For Otic Use in Dogs Only
Do not use in cats

Brief Summary (For Full Prescribing Information, see package insert)

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

DESCRIPTION: DuOtic™ contains 10 mg terbinafine and 1 mg betamethasone acetate per mL and the inactive ingredients propylene carbonate, glycerol formal, hypromellose, phospholipid, oleic acid and butylated hydroxytoluene in an off-white to slightly yellow translucent gel.
INDICATION: DuOtic™ is indicated for the treatment of otitis externa in dogs, associated with susceptible strains of yeast (Malassezia pachydermatis).
CONTRAINDICATIONS: Do not use in dogs with known tympanic perforation. Do not use in dogs with a hypersensitivity to terbinafine or corticosteroids.
WARNINGS:
Human Safety Warnings: DuOtic™ may cause eye injury and irritation.
In case of accidental eye contact, flush thoroughly with water for at least 15 minutes. If wearing contact lenses, rinse eyes first then remove contact lenses and continue to rinse. 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 DuOtic™ 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 eye injury. Avoid hand-to-eye contact. Proper patient selection is important when considering the benefits and risks of using DuOtic™. The use of DuOtic™ in dogs with perforated tympanic membranes has not been evaluated. The integrity of the tympanic membrane should be confirmed before administering each dose of this product. Reevaluate the dog if hearing loss or signs of vestibular dysfunction are observed during treatment.
Changes to the middle ear, such as ulceration of the mucosal lining, have been associated with administration of Osurnia® (florfenicol, terbinafine, betamethasone acetate). The presentation and concentrations of terbinafine and betamethasone acetate in DuOtic™ are identical to the concentrations of these active ingredients in Osurnia®.
Signs of tympanic membrane rupture, internal ear disease such as head tilt, ataxia, nystagmus, facial paralysis, and keratoconjunctivitis sicca have also been reported in relation to the administration of Osurnia®.
Do not administer orally.
Use of topical otic corticosteroids has been associated with adrenocortical suppression and iatrogenic hyperadrenocorticism in dogs.
Use with caution in dogs with impaired hepatic function.
The safe use of DuOtic™ has not been evaluated in dogs that are pregnant, lactating or intended for breeding.
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 DuOtic™ with 1 tube per affected ear(s) and repeated after 7 days: Elevated alanine aminotransferase, Conjunctivitis, Ocular discharge, Ear pruritus.
Post-Approval Experience:
The following adverse events are based on post-approval adverse drug experience reporting for Osurnia® (florfenicol, terbinafine, betamethasone acetate). The presentation and concentrations of terbinafine and betamethasone acetate in DuOtic™ are identical to the concentrations of these active ingredients in 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 to 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 FDA at 1-888-FDA-VETS or online at www.fda.gov/reportanimalae.
INFORMATION FOR DOG OWNERS: Owners should be aware that adverse reactions may occur following administration of DuOtic™ and should observe their dog for signs such as deafness, ear pain and irritation, vomiting, head shaking, head tilt, incoordination, eye pain and ocular discharge. 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 DuOtic™ which may lead to eye exposure. As a result, eye injuries in humans and dogs have been reported including corneal ulcers following the use of a similar product (Osurnia®). Owners should be careful to avoid ocular exposure.

Approved by FDA under NADA # 141-579

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

R 02 2024