

# SIMPLERA™

(florfenicol, terbinafine,  
mometasone furoate)

Otic Solution for use in dogs only

Do Not Use in Cats.

Antibacterial, antifungal, and anti-inflammatory

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

## DESCRIPTION:

SIMPLERA contains 16.6 mg/mL florfenicol, 14.8 mg/mL terbinafine (equivalent to 16.6 mg/mL terbinafine hydrochloride) and 2.2 mg/mL mometasone furoate. Inactive ingredients include purified water, propylene carbonate, propylene glycol, ethyl alcohol, and polyethylene glycol.

## INDICATIONS:

SIMPLERA 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:

**SIMPLERA should be administered by veterinary personnel.**

**Wear eye protection when administering SIMPLERA.**

(see **Human Warnings, PRECAUTIONS, POST-APPROVAL EXPERIENCE**).

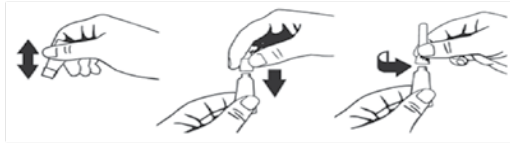
Splatter may occur if the dog shakes its head following administration. Persons near the dog during administration should also take steps to avoid ocular exposure.

**Shake before use.**

**Verify the tympanic membrane is intact prior to administration.** (see **CONTRAINDICATIONS, PRECAUTIONS, POST-APPROVAL EXPERIENCE**).

Administer one dose (1 dropperette) per affected ear.

1. Clean and dry the external ear canal before administering the product.
2. Verify the tympanic membrane is intact prior to administration.
3. Remove single dose dropperette from the package.
4. While holding the dropperette in an upright position, remove the cap from the dropperette.
5. Turn the cap over and push the other end of the cap onto the tip of the dropperette.
6. Twist the cap to break the seal and then remove cap from the dropperette.
7. Screw the applicator nozzle onto the dropperette.



8. Insert the tapered tip of the dropperette into the affected external ear canal and squeeze to instill the entire contents (1 mL) into the affected ear.

9. Gently massage the base of the ear to allow distribution of the solution.

**Restrain the 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**).

10. Repeat with other ear as prescribed.

11. The duration of effect should last 30 days. Cleaning the ear after dosing may affect product effectiveness.

## CONTRAINDICATIONS:

Do not use in dogs with known tympanic membrane perforation (see **PRECAUTIONS**).

SIMPLERA is contraindicated in dogs with known or suspected hypersensitivity to florfenicol, terbinafine hydrochloride, or mometasone furoate.

## WARNINGS:

**Human Warnings:** SIMPLERA may cause eye injury and irritation (see **PRECAUTIONS, POST-APPROVAL EXPERIENCE**).

If contact with eyes occurs, flush copiously with water for at least 15 minutes. If irritation persists, contact a physician.

Humans with known hypersensitivity to any of the active ingredients in SIMPLERA should not handle this product.

Not for use in humans. Keep this and all drugs out of reach of children. Avoid skin contact. In case of accidental ingestion by humans, contact a physician immediately.

## PRECAUTIONS:

**For use in dogs only. Do not use in cats** (see **POST-APPROVAL EXPERIENCE**).

**Wear eye protection when administering SIMPLERA 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 **DOSAGE AND ADMINISTRATION, Human Warnings, POST-APPROVAL EXPERIENCE**).

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

Florfenicol, terbinafine, mometasone furoate otic solution has been associated with rupture of the tympanic membrane. Reevaluate the dog if hearing loss or signs of vestibular dysfunction are observed during treatment.

Signs of internal ear disease such as head tilt, vestibular signs, ataxia, nystagmus, facial paralysis, and keratoconjunctivitis sicca have been reported (see **POST-APPROVAL EXPERIENCE**) with the use of florfenicol, terbinafine, mometasone furoate otic solution.

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**).

The safe use of SIMPLERA™ 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 directly attributable adverse reactions in 146 dogs administered florfenicol, terbinafine, mometasone furoate otic solution.

## POST-APPROVAL EXPERIENCE (2019):

The following adverse events are based on post-approval adverse drug experience reporting for florfenicol, terbinafine, mometasone furoate otic solution. 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 these data.

In **humans**, accidental exposure leading to corneal ulcers and other ocular injuries such as eye irritation and redness have been reported. Exposure occurred when the dog shook its head after application of florfenicol, terbinafine, mometasone furoate otic solution. Skin irritation has also been reported.

In **dogs**, the adverse events reported are presented below in decreasing order of reporting frequency:

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

SIMPLERA is not approved for use in **cats**. The adverse events reported following extra-label use of florfenicol, terbinafine, mometasone furoate otic solution in **cats** are presented below in decreasing order of reporting frequency:

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

To report suspected adverse drug events and/or obtain a copy of the Safety Data Sheet (SDS) or for technical assistance, contact Vetoquinol USA at 1-800-835-9496.

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

## Information for Dog Owners:

Owners should be aware that adverse reactions may occur following administration of SIMPLERA and should be instructed to observe the dog for signs such as ear pain and irritation, vomiting, head shaking, head tilt, incoordination, eye pain and ocular discharge (see **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 SIMPLERA which may lead to ocular exposure. Eye injuries, including corneal ulcers, have been reported in humans and dogs associated with head shaking and splatter following administration. Owners should be careful to avoid ocular exposure (see **PRECAUTIONS, POST-APPROVAL EXPERIENCE**).

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