Florfenicol + Terbinafine + Mometasone Otic - Main

Trade Names:

Claro™ Otic Solution, SIMPLERA™ Otic Solution

GENERAL DESCRIPTION: This drug is a combination ear medication that is used in dogs primarily to treat bacterial, fungal, and inflammatory conditions of the ear. Removing excess debris and wax from an infected ear is an important component of successfully treating ear disease as it allows for ear medications to penetrate deeper into the canal. Florfenicol + Terbinafine + Mometasone Otic is available in the form of single-dose solution dropperettes.

WHAT IS THIS DRUG? A combination product containing an antibiotic (florfenicol), antifungal (terbinafine) and a steroidal anti-inflammatory (mometasone). Applied directly into the ear

REASONS FOR PRESCRIBING: To treat ear external ear infections (otitis externa) in dogs associated with yeast (Malassezia pachydermatis) and bacteria (Staphylococcus pseudintermedius)

WHAT DOGS/CATS SHOULD NOT TAKE THIS MEDICATION?

This medication is only approved for use in dogs with intact ear drums

This mediation is not intended for use in cats

This medication should be used with caution in pets with a history of liver disease

Safe use of this medication in breeding, pregnant, or nursing animals has not been established

Animals with a known hypersensitivity or allergy to this solution should not take this medication

DIRECTIONS: Read and follow the prescription label carefully. This medication is often administered by veterinary professionals. Those administering the medication should consider wearing eye protection to avoid accidental eye exposure. Restraint to minimize head shaking after administration is also important to avoid splatter and inadvertent eye exposure to people nearby. This medication has a duration of activity for 30 days and is administered as a single dose in each affected ear. Do not skip or stop cleaning without consulting your veterinarian. Cleaning frequency may be adjusted based upon an assessment of how your dog is responding clinically. Wait until after the ear is clean and dry before administering any medications into the ear. It may be necessary to clip excess hair from around the ear to assist with cleaning and applying medications. Avoid getting this product in your pet's eyes, nose or mouth. This medication is not intended for oral use. If you are having difficulty cleaning the ear or your pet is in discomfort, contact your veterinarian.

This medication should take effect within 1 to 2 days. You should see improvements in your pet's clinical signs.

Call ahead for refills.

Ideally, give this medication at the same time(s) daily.

CLEANING THE EAR

Use an appropriate ear cleaning solution as directed by your veterinarian

Check label directions and shake the bottle if necessary

Lift the ear flap so that it is pointing straight up

Apply the ear flush liberally into the canal

Massage near the base of the ear to encourage the debris to soften

Allow your pet to shake their head to assist with removal of the fluid and debris

Wipe away any loose debris from the ear flap and canal with a cloth, gauze, or cotton ball

You may need to repeat several times depending on the amount of debris that is present

Do not use cotton applicator swabs in the canal due to potential for injury

Allow the ear and canal to dry for a sufficient period of time prior to installation of medicated drops or ointments

APPLICATION OF EAR MEDICATIONS

The ear should be clean and dry prior to administering medications

Check label directions

Lift the ear flap so that it is pointing straight up

Hold the dropperette with the insertion tip into the canal

This medication is intended as a single dose in each affected ear

Gently squeeze the medication into the canal

Massage near the base of the ear to encourage distribution of the medication into the deeper aspects of the canal

Repeat with opposite ear if necessary

Wash your hands after cleaning and instilling medications into your pet's ears

Always praise and reward your pet to encourage cooperation

WHAT IF A DOSE IS MISSED?

If a dose is missed, give it as soon as you can. If it is time already for the next dose, skip the missed dose and go back to the normal schedule. Do not give two doses at the same time. Remember to allow for drying time if you are also cleaning prior to application of ear medications.

WHAT TO TELL/ASK A VETERINARIAN BEFORE GIVING MEDICATION?

Talk to your veterinarian about:

When your pet will need to be rechecked

How often does your pet's ears need to be cleaned

What tests may need to be performed prior to and during treatment with the ear medication

What are the risks and benefits of using the medication

Tell your veterinarian about:

If your pet has experienced previous ear problems

If your pet has experienced side effects on other drugs/products

If your pet has experienced digestive upset now or ever

If your pet has experienced liver or kidney disease now or ever

If your pet has experienced any other medical problems or allergies now or ever

All medicines and supplements that you are giving your pet or plan to give your pet, including those you can get without a prescription. Your veterinarian may want to check that all of your pet's medications can be given together.

If your pet is pregnant, nursing or if you plan to breed your pet

STORAGE AND WARNINGS:

Florfenicol + Terbinafine + Mometasone Otic should be stored in a childproof container in a cool, dry place at room temperature away from heat and direct sunlight.

Keep this and all medication out of reach of children and pets.

Eye protection should be worn to prevent accidental exposure. In case of accidental eye or contact lens exposure, flush eyes immediately with water and then remove contact lenses. Continue to flush and seek medical advice if symptoms develop. Accidental eye exposure can cause irritation, burning, stinging, redness, itchiness and ulceration.

Owners with an allergy or hypersensitivity to any of the active ingredients should not handle this medication.

Call your physician immediately if you accidentally take this product.

## POTENTIAL SIDE EFFECTS:

This medication is usually well tolerated when used appropriately and intermittently

Prolonged use of any antibiotic may lead to the development of bacterial resistance and overgrowth of other organisms

Topical ear medications containing corticosteroids have been associated with suppression of the adrenal glands and iatrogenic hyperadrenocorticism in dogs

This medication can result in changes to the lining of the middle ear in addition to deafness, ear discharge, ear flap irritation, ear pain and head shaking

This medication can affect the tympanic membrane resulting in internal ear disease causing symptoms such as head tilt, abnormal eye movements (nystagmus), vomiting, fascial paralysis, balance and coordination issues and dry eye (keratoconjunctivitis sicca)

If you notice anything else unusual, contact your veterinarian

This long-acting medication lasts for at least 4-6 weeks but may last longer in pets with kidney or liver disease

## CAN THIS DRUG BE GIVEN WITH OTHER DRUGS?

Do not give new food or medications without first talking to your veterinarian

If your pet experiences any unusual reactions when taking multiple medications, contact your veterinarian

## WHAT SHOULD I DO IF I KNOW OF OR SUSPECT THERE HAS BEEN AN OVERDOSE?

Contact your veterinarian immediately if you pet has accidentally ingested this medication or has received more than the prescribed amount.

## WHAT ELSE SHOULD I KNOW?

Notify your veterinarian if your animal's condition does not improve or worsens despite this treatment.

It is important to have any ear problems assessed by a veterinarian prior to application of medications as incorrect treatment can result in damage to the ear.

It should be given only for the condition for which it was prescribed. Never use ear medications in the eye.

Discuss with your veterinarian what is recommended to treat underlying conditions that may predispose your pet to recurrent ear problems.

This is just a summary of information about Florfenicol + Terbinafine + Mometasone Otic. If you have any questions or concerns about this medication or the condition for which it was prescribed, please contact your veterinarian.