

Rx ONLY



Chloroxylenol 0.1%
Pramoxine HCl 0.5%
Zinc Acetate 0.1%

DESCRIPTION:

Each 1 mL for otic administration contains:
Chloroxylenol 1 mg
Pramoxine HCl 5 mg
Zinc Acetate 1 mg

Also contains: Alpha tocopherol, ascorbic acid, citric acid, edetic acid, glycerin, polysorbate 80, propylene glycol, purified water and sodium hydroxide.

Chloroxylenol is a broad spectrum bactericidal agent which occurs as white crystals with a phenolic odor. It is soluble in alcohol, ether, and alkali hydroxides. Chemically it is 4-chloro-3,5-xyleneol.

Pramoxine Hydrochloride is a topical anesthetic proven to be safe and effective in hospital tests. It occurs as white to practically white crystalline powder, having a numbing taste and it may have a slight aromatic odor. It is freely soluble in water and in alcohol; soluble in chloroform; and very slightly soluble in ether. Chemically it is 4-[3-(4-butoxyphenoxy)propyl]-Morpholine hydrochloride.

Zinc acetate in the dihydrate form is a salt of zinc and is a topical skin protectant generally recognized as safe and effective. Zinc acetate occurs as white crystals or granules, freely soluble in water and in boiling alcohol, and slightly soluble in alcohol. Chemically its structural formula is $C_4H_6O_4Zn \cdot 2H_2O$.

CLINICAL PHARMACOLOGY:

This product is effective as both an antibacterial and antifungal agent. **Chloroxylenol** in low concentrations is a germicide that may be used to treat bacterial and fungal infections. It is a halogenated phenol, non-toxic, non-corrosive, non-staining with a high phenol coefficient. It may be applied directly to a wound and shows no chemical reactivity toward blood. **Pramoxine Hydrochloride** is a topical anesthetic which is chemically unrelated to procaine and other "caines". It provides temporary relief from itching and pain by stabilizing the neuronal membranes of nerve endings with which it comes into contact. **Zinc acetate** temporarily protects injured or exposed skin surfaces from harmful stimuli, and may help provide relief to such surfaces.

INDICATIONS AND USAGE:

For the treatment of superficial infections of the external ear caused by organisms susceptible to the action of the antimicrobial agent and to control the accompanying pain and itching.

CONTRAINDICATIONS:

This medication is contraindicated in patients sensitive to any of the components of this preparation. This medication should not be applied in the external auditory canal where there is a perforated eardrum or when this medication can reach the middle ear.

WARNINGS:

This product is not intended for ophthalmic or oral use. If irritation or sensitization occurs, promptly discontinue use of this preparation and institute other measures.

PRECAUTIONS:

General: Treatment should not be continued for longer than ten days and the source of infection and/or inflammation or sensitization evaluated to determine whether therapy should be changed.

Information For Patients: Patients using this medication should be advised of the following:

1. This medication is to be used as directed by a physician.
2. Do not use this medication for any disorder other than for which it was prescribed. Check with your physician before using this medication for future ear problems.
3. Report any signs of local adverse reactions to your physician.
4. Keep this and all medications out of the reach of children. In case of accidental overdose or ingestion, seek professional assistance or contact a poison control center immediately.
5. Store at controlled room temperature 59°-86°F (15°-30°C).

Carcinogenesis, Mutagenesis, Impairment of Fertility: No long term studies have been performed to evaluate the carcinogenic or mutagenic potential of this product.

Pregnancy: Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. ZINOTIC should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

ADVERSE REACTIONS:

The following adverse reactions with topical pramoxine have been reported: redness, irritation, swelling, burning, stinging, pain or dryness at the affected area.

DOSAGE AND ADMINISTRATION:

The external ear, that is the auricle and the auditory canal, should be thoroughly cleansed and dried.

Adults: Four (4) to five (5) drops of ZINOTIC should be instilled into the affected ear 3 times daily but not more than 4 times daily.

Children 2 years of age and older: Because

of the smaller capacity of the ear canal, three (3) drops of ZINOTIC should be instilled into the affected ear 3 times daily but not more than 4 times daily. Children under 2 years: as directed by a physician.

The patient should lie with the affected ear upward, pulling the outer earlobe upward and backward, to instill the drops. The patient should maintain this position for up to 5 minutes to facilitate penetration of the drops into the ear canal. Repeat, if necessary for the opposite affected ear.

If preferred, a gauze ear plug or wick may be inserted into the ear canal prior to applying ZINOTIC drops. When using a wick, a few drops of sterile water should be applied directly to the wick following insertion to facilitate hydration. It should then be saturated with ZINOTIC. The patient should be instructed to add a few drops of ZINOTIC to the wick every four hours, and to remove the wick after 24 hours. Five (5) drops of ZINOTIC should continue to be instilled 3 or 4 times daily thereafter. When using a gauze earplug, the external ear canal is first treated with drops of ZINOTIC. Next, the gauze is inserted into the ear canal to contain medication. The gauze ear plug or the expanded wick is easily removed by fingers, forceps, or tweezers. This product may continue to be used in the unaffected ear 3 times daily as a preventative.

HOW SUPPLIED:

ZINOTIC ear drops are supplied as a slightly yellow liquid in white plastic dropper bottles containing 15 mL, NDC 24338-711-15 and bottles containing 2 mL, NDC 24338-711-02.

Store at controlled room temperature 59°-86°F (15°-30°C). Protect from light. Avoid freezing. Dispense in original container.

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KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN. IN CASE OF ACCIDENTAL OVERDOSE, SEEK PROFESSIONAL ASSISTANCE OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

U.S. Patent # 6,093,417; patent pending

Manufactured for:



Raleigh, NC 27609
www.arborpharma.com

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