

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

40166

DRAFT FINAL PRINTED LABELING

ACETIC ACID OTIC SOLUTION USP, 2%
PRODUCT CODE 8741
15 mL FINAL PRINTED PACKAGE INSERT



ACETIC ACID
OTIC SOLUTION USP, 2%

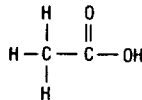
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APPROVED

DESCRIPTION

Acetic Acid Otic Solution, USP is a nonaqueous solution of glacial acetic acid, USP (2%), in a propylene glycol vehicle containing benzethonium chloride, USP (0.02%); propylene glycol diacetate, NF (3%) and sodium acetate, USP (0.015%). It may also contain citric acid, USP.

The molecular formula for acetic acid is CH_3COOH , with a molecular weight of 60.05. The structural formula is:



Acetic Acid Otic Solution is available as a nonaqueous otic solution buffered at pH 3 for use in the external ear canal.

CLINICAL PHARMACOLOGY

Acetic acid is anti-bacterial and anti-fungal; propylene glycol is hydrophilic and provides a low surface tension; benzethonium chloride is a surface active agent that promotes contact of the solution with tissues.

INDICATIONS AND USAGE

For the treatment of superficial infections of the external auditory canal caused by organisms susceptible to the action of the antimicrobial.

CONTRAINDICATIONS

Hypersensitivity to Acetic Acid Otic Solution or any of the ingredients. Perforated tympanic membrane is frequently considered a contraindication to the use of any medication in the external ear canal.

WARNINGS

Discontinue promptly if sensitization or irritation occurs.

PRECAUTIONS

Transient stinging or burning may be noted occasionally when the solution is first instilled into the acutely inflamed ear.

ADVERSE REACTIONS

Stinging or burning may be noted occasionally; local irritation has occurred very rarely.

DOSAGE AND ADMINISTRATION

Carefully remove all cerumen and debris to allow Acetic Acid Otic Solution to contact infected surfaces directly. To promote continuous contact, insert a wick saturated with the solution into the ear canal; the wick may also be saturated after insertion. Instruct the patient to keep the wick in for at least 24 hours and to keep it moist by adding 3 to 5 drops of the solution every 4 to 6 hours. The wick may be removed after 24 hours but the patient should continue to instill 5 drops of Acetic Acid Otic Solution 3 or 4 times daily thereafter, for as long as indicated.

HOW SUPPLIED

Acetic Acid Otic Solution USP, 2% is supplied in 15 mL measured drop, safety-tip plastic bottles.

RECOMMENDED STORAGE

Store at controlled room temperature, 15°-30°C (59°-86°F).

KEEP CONTAINER TIGHTLY CLOSED

CAUTION: Federal law prohibits dispensing without prescription.

Product No.: 8741

Manufactured By:
Morton Grove Pharmaceuticals, Inc.
Morton Grove, IL 60053

new

**ACETIC ACID OTIC SOLUTION USP, 2%
PRODUCT CODE 8741
15 mL FINAL PRINTED CONTAINER LABELING**

5 60432-741-15-84



Contains Glacial Acetic Acid, USP, 2%
Acetic Acid Otic Solution, USP, 2%
propylene glycol vehicle containing
benzalkonium chloride, USP; propylene glycol
also contains citric acid, USP

MGP
NDC 60432-741-15
**ACETIC ACID
OTIC
SOLUTION
USP, 2%**
CAUTION: Federal law prohibits
dispensing without prescription.
NET CONTENTS: 15 mL

DO NOT USE IF RIMMO PRINTED SEALING FOR YOUR
PROTECTION. ADDING CAP IS BROKEN OR MISSING.
WARNING: KEEP THIS AND ALL DRUGS OUT
OF THE REACH OF CHILDREN. In case of accidental
ingestion, seek professional advice or contact a
poison control center. Store at controlled room temperature.
KEEP CONTAINER TIGHTLY CLOSED.
Manufactured by: Marion Greer
Pharmaceuticals, Inc., Indianapolis, IN 46205
SRN1115 US 546