Acetic Acid Otic Solution USP, 2%

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 \( \text{CH}_3\text{COOH} \), with a molecular weight of 60.05. The structural formula is:

\[
\begin{align*}
\text{H} & \quad \text{O} \\
\mid & \quad \mid \\
\text{H} & \quad \text{C} \quad \text{C} \quad \text{OH} \\
\mid & \quad \\
\text{H} & \\
\end{align*}
\]

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 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.

PEDIATRIC USE
Safety and effectiveness in pediatric patients below the age of 3 years have not been established.

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 of cotton 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. In pediatric patients, 3 to 4 drops may be sufficient due to the smaller capacity of the ear canal.

HOW SUPPLIED
Acetic Acid Otic Solution USP, 2% is available in 15 mL (NDC 64980-424-15) measured-drop, safety-tip plastic bottles.

STORAGE
Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]
KEEP CONTAINER TIGHTLY CLOSED
Rx Only
Manufactured by:
Bio-Pharm, Inc.
Levittown, PA 19057
Distributed by:
Rising Pharmaceuticals, Inc.
Saddle Brook, NJ 07663
Rev. 05/2018

PRINCIPAL DISPLAY PANEL - 15 mL bottle
Rising®
NDC 64980-424-15
Acetic Acid Otic
Solution USP, 2%
DO NOT USE IF BAND PRINTED
"SEALED FOR YOUR PROTECTION"
AROUND CAP IS BROKEN OR MISSING.
15 mL
Rx only
PRINCIPAL DISPLAY PANEL - 15 mL Carton

Rising®

NDC 64980-424-15

Acetic Acid

Otic Solution

USP, 2%

DO NOT USE IF BAND PRINTED "SEALED FOR YOUR PROTECTION" AROUND CAP IS BROKEN OR MISSING.

15mL

Rx only
ACETIC ACID
acetic acid solution

Product Information

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<tr>
<td><strong>Product Type</strong></td>
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<td><strong>Route of Administration</strong></td>
<td>AURICULAR (OTIC)</td>
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<td><strong>Item Code (Source)</strong></td>
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Active Ingredient/Active Moiety

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<th>Basis of Strength</th>
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<tr>
<td>ACETIC ACID (UNII: Q40Q9N063P) (ACETIC ACID - UNII:Q40Q9N063P)</td>
<td>ACETIC ACID</td>
<td>20 mg in 1 mL</td>
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Inactive Ingredients

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<tr>
<th>Ingredient Name</th>
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<tr>
<td>PROPYLENE GLYCOL DIACETATE (UNII: 5Z492UNF9O)</td>
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RISING PHARMACEUTICALS, INC.

**Components:**
- **Propylene Glycol Diacetate** (UNII: 5Z492UNF9O)
- **Benzethonium Chloride** (UNII: PH41D05744)
- **Sodium Acetate** (UNII: 4550K0SC9B)
- **Anhydrous Citric Acid** (UNII: XF417D3PSL)
- **Propylene Glycol** (UNII: 6DC9Q167V3)

**Packaging:**

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<td>1 in 1 CARTON</td>
<td>03/14/2018</td>
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<td>1</td>
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<td>15 mL in 1 BOTTLE; Type 0: Not a Combination Product</td>
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**Marketing Information:**

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<td>03/14/2018</td>
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**Labeler** - Rising Pharmaceuticals, Inc. (041241766)

Revised: 6/2018

Rising Pharmaceuticals, Inc.