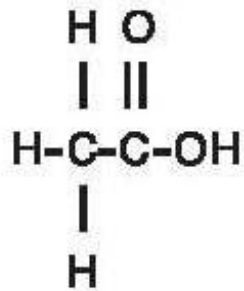


**ACETIC ACID- acetic acid solution**  
**Quality Care Products LLC**

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**Acetic Acid Otic Solution, USP**

**DESCRIPTION**

Acetic Acid Otic Solution, USP is a solution of acetic acid (2%), in a propylene glycol vehicle containing propylene glycol diacetate (3%), benzethonium chloride (0.02%), and sodium acetate (0.015%). The empirical formula for acetic acid is CH<sub>3</sub>COOH, with a molecular weight of 60.05. The structural formula is:



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

**CLINICAL PHARMACOLOGY**

Acetic acid is antibacterial and antifungal; 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 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 to contact infected surfaces directly. To promote continuous contact, insert a wick of cotton saturated with Acetic Acid 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 Acetic Acid 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 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 containing 2% acetic acid, is available in 15 mL (NDC 55700-424-15) measured-drop, safety-tip plastic bottles.

## **STORAGE**

Store at 20°- 25°C (68°-77°F). Keep container tightly closed.

Hi-Tech Pharmacal Co., Inc.

Amityville, NY 11701

MG# 28428

Rev. 889:02 11/09



See Full Prescribing Information Store at 68-77 degrees F.

Holland, OH 43528

**Acetic Acid Otic Solution, USP**

**GTIN: 00355700424152**  
**NDC: 55700-424-15**  
**Serial:**  
**Lot:**  
**EXP: //**

**#15 mL**

Rx only

Acetic Acid is a nonaqueous solution of Acetic Acid (2%)

Keep all medication out of reach of children



Mfr: HI-TECH PHARMACAL CO., INC., Amityville, N.Y. 11701

**ACETIC ACID**

acetic acid solution

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:55700-424(NDC:50383-889)
<b>Route of Administration</b>	AURICULAR (OTIC)		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>ACETIC ACID</b> (UNII: Q40Q9N063P) (ACETIC ACID - UNII:Q40Q9N063P)	ACETIC ACID	20.65 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>BENZETHONIUM CHLORIDE</b> (UNII: PH41D05744)	
<b>PROPYLENE GLYCOL DIACETATE</b> (UNII: 5Z492UNF90)	
<b>SODIUM ACETATE</b> (UNII: 4550K0SC9B)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55700-424-15	1 in 1 BOX	08/05/2016	
1		15 mL in 1 BOTTLE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
NDA	NDA012179	01/22/2010	

**Labeler** - Quality Care Products LLC (831276758)

### **Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Quality Care Products LLC		831276758	relabel(55700-424)

Revised: 2/2023

Quality Care Products LLC