

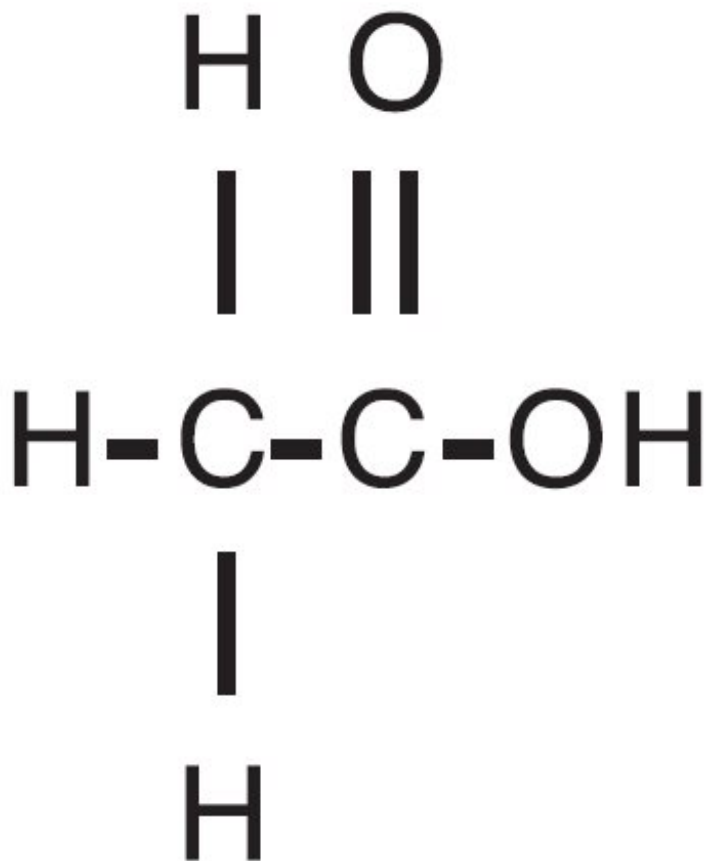
**ACETIC ACID- acetic acid solution**  
**NuCare Pharmaceuticals, Inc.**

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**Acetic Acid Otic Solution, USP**

**Rx only**

**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 68071-1739-5 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

Rev. 889:02 11/09

## PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

**NuCare Pharmaceuticals, Inc.**

NDC: 68071-1739-5

**Acetic Acid**

**15mL Otic Soln.**

See manufacturer's label for full list of ingredients.

Product #: R0815015

**Rx Only**

Acetic Acid  
Lot: 000000 NDC: 68071-1739-05  
MFR NDC: 50383-889-15 Exp.: 00-00  
Serial# 00000000002

Acetic Acid  
Lot: 000000 NDC: 68071-1739-05  
MFR NDC: 50383-889-15 Exp.: 00-00  
Serial# 00000000002

GTIN 00368071173956  
Serial# 00000000002  
Exp. Date 00-00  
LOT#: 000000

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Manufactured by: 3  
Hi-Tech Pharmacal Co., Inc.  
Amityville, N.Y. 11701  
Packed By:  
NuCare Pharmaceuticals, Inc.  
Orange, CA 92667

Instill \_\_\_\_\_ drops  
\_\_\_\_\_ times a day.

6807117390518-000000-000000

Rev. 01/01/19

WARNING: KEEP OUT OF REACH OF CHILDREN

STORE AT CONTROLLED TEMPERATURE 68-77°F.

## ACETIC ACID

acetic acid solution

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:68071-1739(NDC:50383-889)
Route of Administration	AURICULAR (OTIC)		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
BENZETHONIUM CHLORIDE (UNII: PH41D05744)	
PROPYLENE GLYCOL DIACETATE (UNII: 5Z492UNF9O)	
SODIUM ACETATE (UNII: 4550K0SC9B)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-1739-5	15 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/27/2018	

**Marketing Information**

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

**Labeler** - NuCare Pharmaceuticals,Inc. (010632300)**Establishment**

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	relabel(68071-1739)

Revised: 2/2021

NuCare Pharmaceuticals,Inc.