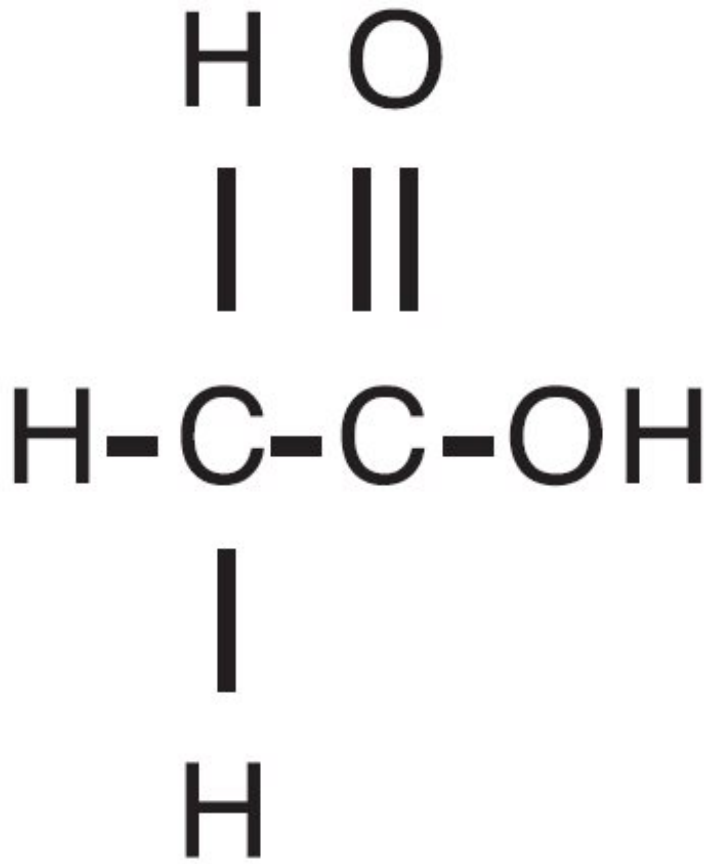
ACETIC ACID- acetic acid solution
NuCare Pharmaceuticals,Inc.

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_3COOH, 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

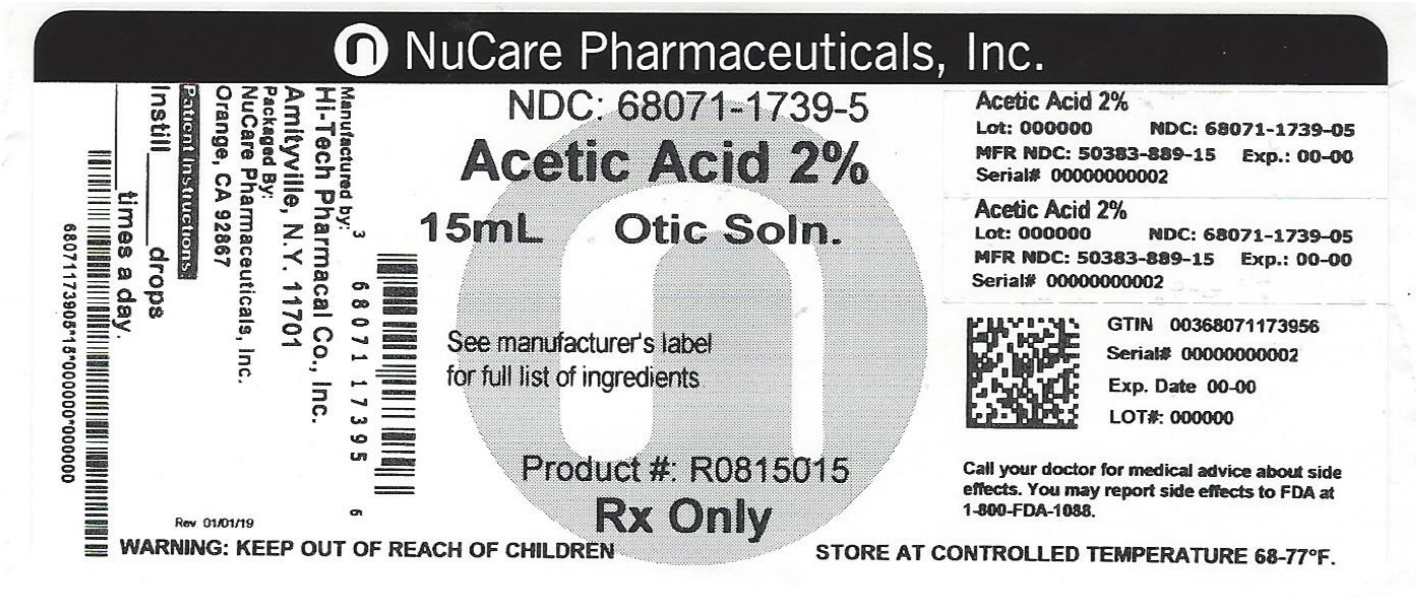
Store at 20°- 25°C (68°-77°F). Keep container tightly closed.

Hi-Tech Pharmacal Co., Inc.

Amityville, NY 11701

Rev. 889:02 11/09

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL



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: 8/2019 NuCare Pharmaceuticals,Inc.