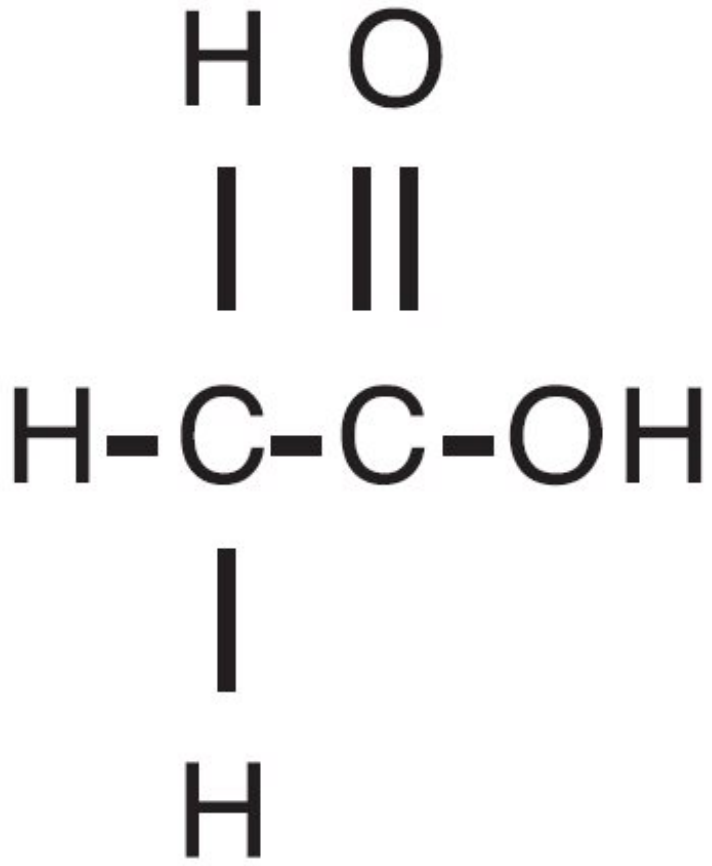
ACETIC ACID- acetic acid solution
NuCare Pharmaceuticals,Inc.

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%), sodium acetate (0.015%), and citric acid. The molecular formula for acetic acid is CH_3COOH, with a molecular weight of 60.05. The structural formula is:



Acetic acid otic solution, USP 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 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.

To report SUSPECTED ADVERSE REACTIONS, contact Saptalis Pharmaceuticals, LLC at 1-833-727-8254 or FDA at 1800-FDA-1088 or *www.fda.gov/medwatch.*

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 acetic acid otic 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 drops to 5 drops of acetic acid otic solution every 4 hours 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 times or 4 times daily thereafter, for as long as indicated. In pediatric patients, 3 drops 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 measured-drop, safety-tip plastic bottles.

NDC 68071-2984-5 15 mL Bottle

STORAGE

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Keep container tightly closed.

Manufactured by:

Saptalis Pharmaceuticals, LLC

Hauppauge, NY 11788

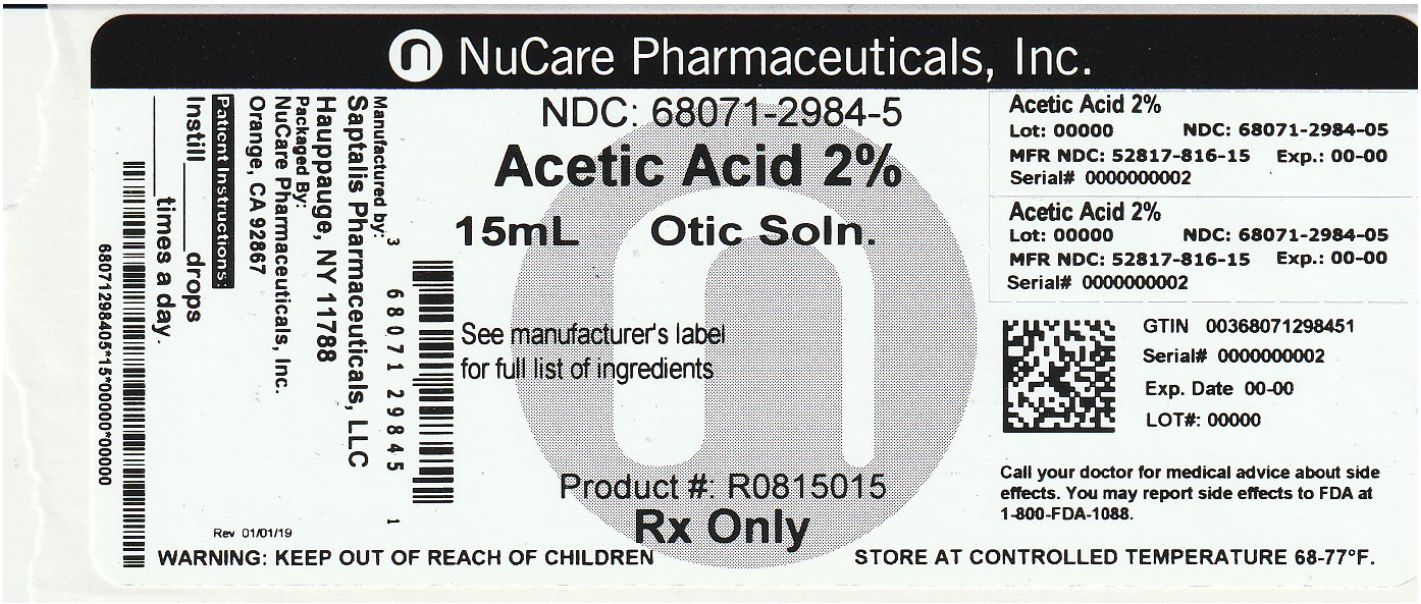
Distributed by:

TruPharma, LLC

Tampa, FL 33609

Rev. 03/20-R1

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL



ACETIC ACID

acetic acid solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:68071-2984(NDC:52817-816)
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)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-2984-5	1 in 1 CARTON	04/19/2023	
1		15 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040607	06/05/2020	

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	relabel(68071-2984)

Revised: 4/2023 NuCare Pharmaceuticals,Inc.