

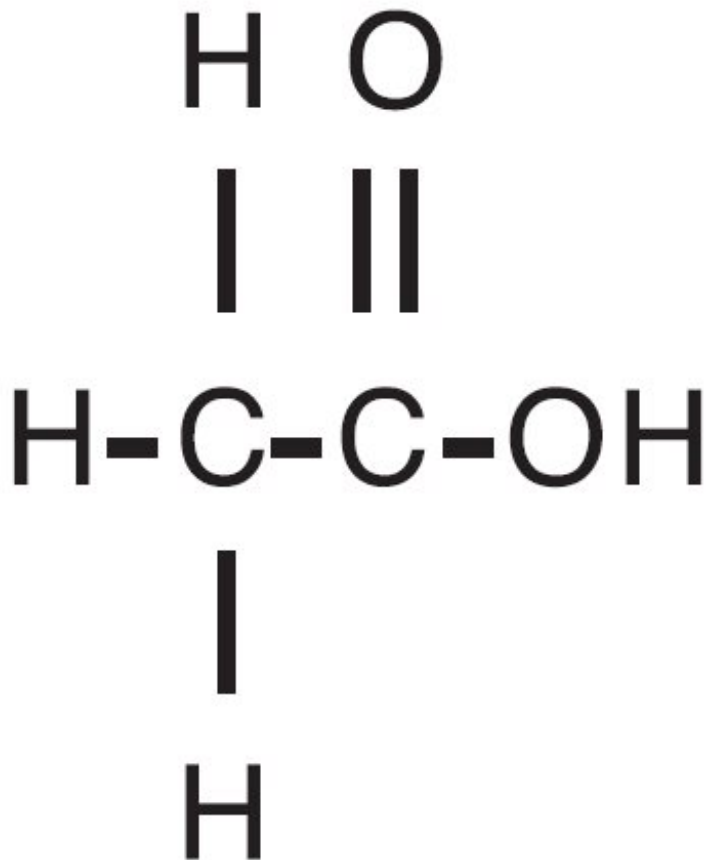
**ACETIC ACID- acetic acid solution**  
**A-S Medication Solutions**

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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%), sodium acetate (0.015%), and citric acid. The molecular formula for acetic acid is CH<sub>3</sub>COOH, 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](http://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**

Product: 50090-6527

NDC: 50090-6527-0 15 mL in a BOTTLE / 1 in a CARTON

## 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

## ACETIC ACID



## ACETIC ACID

acetic acid solution

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:50090-6527(NDC:52817- 816)
<b>Route of Administration</b>	AURICULAR (OTIC)		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>ACETIC ACID</b> (UNII: Q40Q9N063P) (ACETIC ACID - UNII:Q40Q9N063P)		ACETIC ACID	20.65 mg in 1 mL	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>				<b>Strength</b>
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
BENZETHONIUM CHLORIDE (UNII: PH41D05744)				
PROPYLENE GLYCOL DIACETATE (UNII: 5Z492UNF9O)				
SODIUM ACETATE (UNII: 4550K0SC9B)				
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:50090-6527-0	1 in 1 CARTON	06/15/2023	
1		15 mL in 1 BOTTLE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA040607		06/05/2020	

**Labeler** - A-S Medication Solutions (830016429)

### Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-6527)

Revised: 6/2023

A-S Medication Solutions