

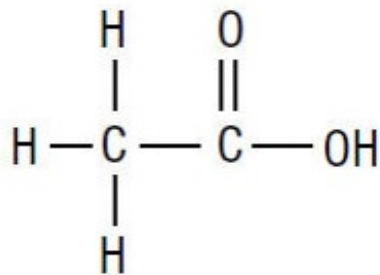
ACETIC ACID- acetic acid solution
Chartwell RX, LLC

ACETIC ACID OTIC SOLUTION, USP

DESCRIPTION

Acetic Acid Otic Solution, USP is a colorless to pale yellow color nonaqueous solution of glacial acetic acid (2%), in a propylene glycol vehicle containing benzethonium chloride, propylene glycol diacetate, and sodium acetate trihydrate. **It may also contain** citric acid anhydrous.

The molecular formula for acetic acid is CH₃COOH, 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 anti-bacterial and anti-fungal; 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.

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 the 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 to 5 drops of the solution 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 otic solution 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, 2% is a colorless to pale yellow color solution supplied in 15 mL bottle with dropper plug and extended TIP closure.

They are available as follows:

Bottle of 15 mL – NDC 62135-801-51

RECOMMENDED STORAGE

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

KEEP CONTAINER TIGHTLY CLOSED

Rx Only

Manufactured for:

Chartwell RX, LLC.

Congers, NY 10920

L71805

Rev: 03/2024

PRINCIPAL DISPLAY PANEL

Acetic Acid Otic Solution, USP 2% - NDC 62135-801-51 - 15 mL Bottle Label

NDC 62135-801-51

Acetic Acid Otic Solution, USP

2%

Rx Only
NET CONTENTS 15 mL

Chartwell Rx

Contains Glacial Acetic Acid, USP..... 2%
 Acetic Acid Otic Solution, USP is a nonaqueous solution of glacial acetic acid (2%) in a propylene glycol vehicle containing benzethonium chloride; propylene glycol diacetate, and sodium acetate trihydrate. **It may also contain** citric acid anhydrous.


USUAL DOSAGE: See accompanying package insert.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. KEEP CONTAINER TIGHTLY CLOSED

Manufactured For: Chartwell RX, LLC.
 Congers, NY 10920

GTIN 00362135801519 L71804 REV.01 03/24



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No Varnish

ACETIC ACID

acetic acid solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:62135-801
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 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
BENZETHONIUM CHLORIDE (UNII: PH41D05744)	
PROPYLENE GLYCOL DIACETATE (UNII: 5Z492UNF90)	
SODIUM ACETATE (UNII: 4550K0SC9B)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Product Characteristics

Color	yellow (colorless to pale yellow)	Score	
Shape		Size	
Flavor		Imprint Code	

Contains**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62135-801-51	15 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/25/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040166	07/26/1996	

Labeler - Chartwell RX, LLC (079394054)

Revised: 3/2024

Chartwell RX, LLC