

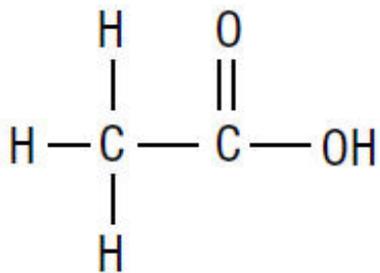
ACETIC ACID- acetic acid solution
Unit Dose Services

ACETIC ACID OTIC SOLUTION USP, 2%

DESCRIPTION

Acetic Acid Otic Solution, USP is a nonaqueous solution of glacial acetic acid, USP (2%), in a propylene glycol vehicle containing benzethonium chloride, USP (0.02%); propylene glycol diacetate, NF (3%) and sodium acetate, USP (0.015%). **It may also contain** citric acid, USP.

The molecular formula for acetic acid is CH₃COOH, with a molecular weight of 60.05. The structural formula is:



Acetic Acid Otic Solution 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

Product: 50436-4600

NDC: 50436-4600-1 15 mL in a BOTTLE

ACETIC ACID SOLUTION

NDC:50436-4600-1
ACETIC ACID OTIC
SOLUTION, USP
2 % / 15 ML

Contains Glacial Acetic Acid, USP.....2 %
WARNING: KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25°C(68-77°F) CONTROLLED ROOM TEMPERATURE. SEE PACKAGE INSERT FOR DOSAGE INFORMATION.



MFG BY: MEDVAC GROUP, INC., MORTON GROVE, IL 60053
MFG NDC: 60432-741-15
MFG LOT: XXXXX
LOT: XXXXX EXP: XXXXX
Pkg by: Unit Dose Services, LLC
Dania, FL 33004 **RX ONLY**

NDC: 50436-4600-1
DRUG: ACETIC ACID OTIC SOLUTION, USP 2 % / 15 ML
LOT: XXXXX EXP: XXXXX

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LOT: XXXXX EXP: XXXXX

ACETIC ACID

acetic acid solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:50436-4600(NDC:60432-741)
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)	
PROPYLENE GLYCOL DIACETATE (UNII: 5Z492UNF9O)	
BENZETHONIUM CHLORIDE (UNII: PH41D05744)	
SODIUM ACETATE (UNII: 4550K0SC9B)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50436-4600-1	15 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/26/1996	

Marketing Information

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

Labeler - Unit Dose Services (831995316)

Establishment

Name	Address	ID/FEI	Business Operations
Unit Dose Services		831995316	REPACK(50436-4600) , RELABEL(50436-4600)

Revised: 11/2017

Unit Dose Services