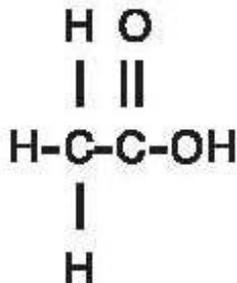


ACETIC ACID- acetic acid solution
Rebel Distributors Corp

Acetic Acid Otic Solution, USP

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 CH₃COOH, 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 21695-222-15) 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

MG# 28428

Rev. 889:02 11/09

Repackaged by:

Rebel Distributors Corp

Thousand Oaks, CA 91320

PRINCIPAL DISPLAY PANEL

PHYSICIAN PARTNER
A DIVISION OF HALL, LINDBERG & COMPANY

NDC 21695-222-15

Acetic Acid 2%
15ml Otic Solution

Each bottle contains: Acetic Acid Otic Solution, USP, containing 2% Acetic Acid

See package insert

Product ID: RA022215

Mfr. By: Hi-Tech Pharmacal Co., Inc. Amityville, N.Y. 11701 Made in U.S.A.

Peel

Acetic Acid 2%
15ml Otic Solution
Lot #:00000
NDC 21695-222-15

Acetic Acid 2%
15ml Otic Solution
Lot #:00000
NDC 21695-222-15

Lot #:00000

EXP. 00/00/00

RA022215

Peel

Acetic Acid 2%
15ml Otic Solution
Lot #:00000
NDC 21695-222-15

Acetic Acid 2%
15ml Otic Solution
Lot #:00000
NDC 21695-222-15

Distributed by: Physician Partner, Thousand Oaks, CA 91320 www.physicianpartner.com
Store at controlled room temperature 15°-30°C (59°-86°F) Keep medication out of the reach of children.

ACETIC ACID			
acetic acid solution			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:21695-222(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:21695-222-15	1 in 1 BOX		
1		15 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA012179	01/22/2010	

Labeler - Rebel Distributors Corp (118802834)**Establishment**

Name	Address	ID/FEI	Business Operations
Rebel Distributors Corp		118802834	RELABEL, REPACK

Revised: 12/2011

Rebel Distributors Corp