

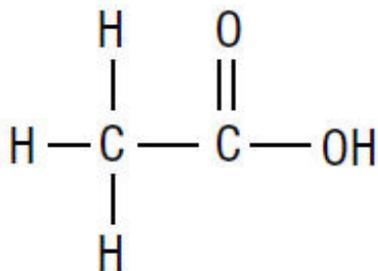
**ACETIC ACID- acetic acid solution**  
**Morton Grove Pharmaceuticals, Inc.**

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**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 CH<sub>3</sub>COOH, 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**

Acetic Acid Otic Solution USP, 2% is supplied in 15 mL measured drop, safety-tip plastic bottles.

**RECOMMENDED STORAGE**

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

**KEEP CONTAINER TIGHTLY CLOSED****Rx Only**

Product No.: 8741

**Manufactured For:**

**Wockhardt USA, LLC**

**Parsippany, NJ 07054**

**Manufactured By:**

**Morton Grove Pharmaceuticals, Inc**

**Morton Grove, IL 60053**

A50-8741-15

REV. 09-12

**PRINCIPAL DISPLAY PANEL****MGP**

NDC 60432-741-15

**ACETIC ACID****OTIC****SOLUTION**

**USP, 2%**

**DO NOT USE IF BAND**

PRINTED "SEALED FOR YOUR  
PROTECTION" AROUND CAP  
IS BROKEN OR MISSING.

**Rx Only**

**NET CONTENTS:**

**15 mL**

**MGP**

**NDC 60432-741-16**

**ACETIC ACID**

**OTIC**

**SOLUTION**

**USP, 2%**

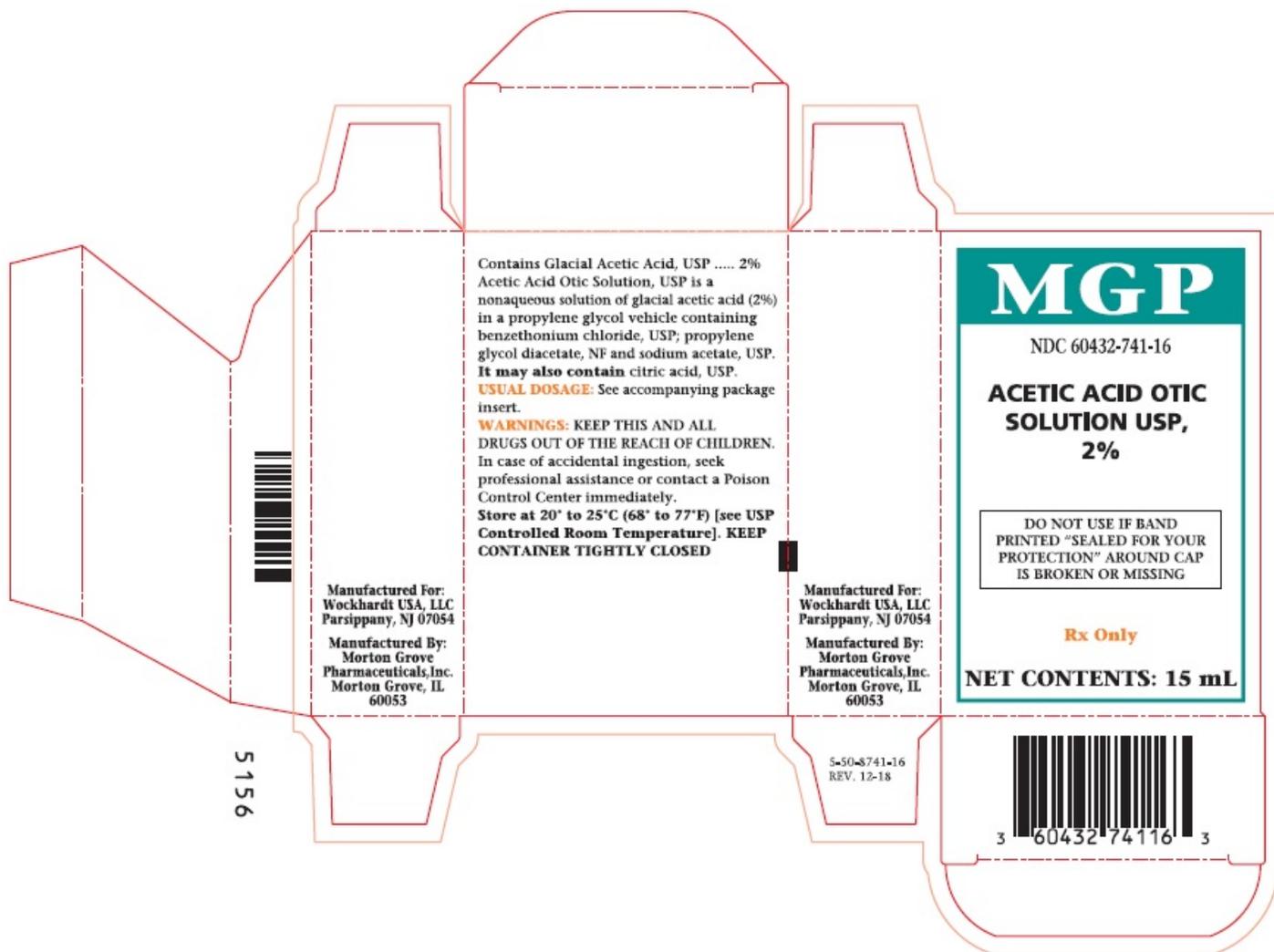
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**Rx Only**

**NET CONTENTS:**

**15 mL**



Acetic Acid Carton

ACETIC ACID			
acetic acid solution			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	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:60432-741-15	15 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/26/1996	
2	NDC:60432-741-16	1 in 1 CARTON	01/04/2019	
2	NDC:60432-741-15	15 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

### Marketing Information

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

**Labeler** - Morton Grove Pharmaceuticals, Inc. (801897505)

**Registrant** - Morton Grove Pharmaceuticals, Inc. (801897505)

### Establishment

Name	Address	ID/FEI	Business Operations
Morton Grove Pharmaceuticals, Inc.		801897505	ANALYSIS(60432-741) , LABEL(60432-741) , MANUFACTURE(60432-741) , PACK(60432-741)

Revised: 1/2019

Morton Grove Pharmaceuticals, Inc.