

HYDROCORTISONE AND ACETIC ACID- hydrocortisone and acetic acid solution

Sun Pharmaceutical Industries, Inc.

**Hydrocortisone 1%
and Acetic Acid 2%
Otic Solution**

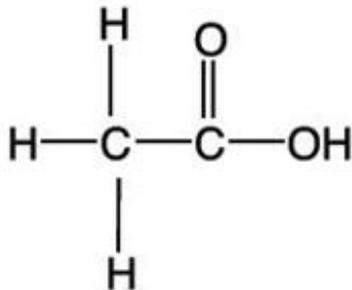
(Hydrocortisone and Acetic Acid Otic Solution, USP)

Rx only

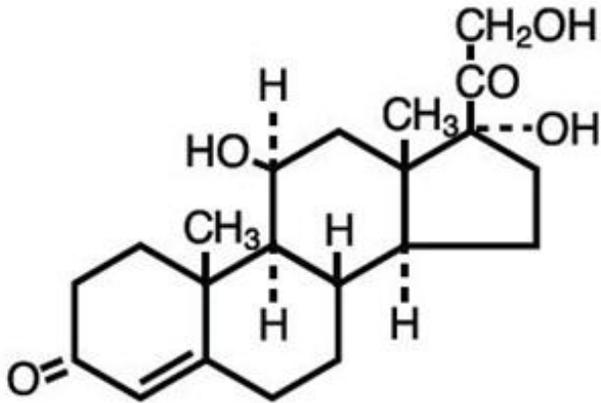
DESCRIPTION

Hydrocortisone and Acetic Acid Otic Solution, USP contains Hydrocortisone (1%) and acetic acid, glacial (2%) in a propylene glycol vehicle containing benzethonium chloride (0.02%), citric acid (0.2%), propylene glycol diacetate (3%) and sodium acetate (0.015%).

Acetic acid has a molecular formula of CH_3COOH with molecular weight of 60.05. The structural formula is:



Hydrocortisone is a Synthetic Steroid used as an anti-inflammatory and antipruritic agent. Its chemical name is Pregn-4-ene-3,20-dione, 11, 17, 21-trihydroxy-, (11 β)-. Hydrocortisone has a molecular formula of $\text{C}_{21}\text{H}_{30}\text{O}_5$ with molecular weight 362.46. The structural formula is:



Hydrocortisone and acetic acid is available as a non-aqueous otic solution buffered at pH (2.0 to 4.0) for use in the external ear canal.

CLINICAL PHARMACOLOGY

Acetic acid is anti-bacterial and antifungal; hydrocortisone is anti-inflammatory, antiallergic and antipruritic; 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, complicated by inflammation.

CONTRAINDICATIONS

Hypersensitivity to hydrocortisone and acetic acid otic solution or any of the ingredients; herpes simplex, vaccinia and varicella. 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 hydrocortisone 1% and acetic acid 2% 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 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

Hydrocortisone 1% and acetic acid 2% otic solution is available in 10 mL plastic, controlled dropper tip bottle.

10 mL bottle

NDC 51672-3007-1

Store at 20° to 25°C (68° to 77°F)[see USP Controlled Room Temperature]. Protect from freezing. Keep container tightly closed.

Mfd. by: Taro Pharmaceuticals Inc.
Brampton, Ontario, Canada L6T 1C1
Dist. by: **Taro Pharmaceuticals U.S.A., Inc.**
Hawthorne, NY 10532

Revised: May, 2015

PK-4785-1

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0515-1

PRINCIPAL DISPLAY PANEL - 10 mL Bottle Carton

10 mL

NDC 51672-3007-1

**Hydrocortisone 1%
and Acetic Acid 2%
Otic Solution USP**

FOR OTIC USE ONLY.

**Keep this and all
medications out of the
reach of children.**

Rx only

TARO



HYDROCORTISONE AND ACETIC ACID

hydrocortisone and acetic acid solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:51672-3007
Route of Administration	AURICULAR (OTIC)		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	10.4 mg in 1 mL
ACETIC ACID (UNII: Q40Q9N063P) (ACETIC ACID - UNII:Q40Q9N063P)	ACETIC ACID	20.8 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM ACETATE (UNII: 4550K0SC9B)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLENE GLYCOL DIACETATE (UNII: 5Z492UNF9O)	
BENZETHONIUM CHLORIDE (UNII: PH41D05744)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51672-3007-1	1 in 1 CARTON	04/28/2005	
1		10 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA088759	04/28/2005	

Labeler - Sun Pharmaceutical Industries, Inc. (146974886)**Establishment**

Name	Address	ID/FEI	Business Operations
Sun Pharma Canada Inc.		243339023	manufacture(51672-3007)

Revised: 7/2025

Sun Pharmaceutical Industries, Inc.