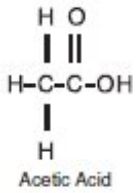
HYDROCORTISONE AND ACETIC ACID- hydrocortisone and acetic acid solution
Akorn Operating Company LLC

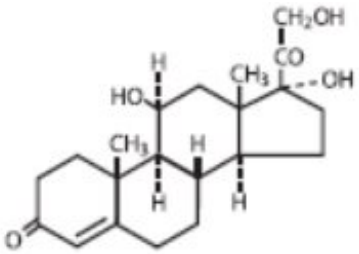
Hydrocortisone and Acetic Acid Otic Solution, USP

DESCRIPTION

Hydrocortisone and Acetic Acid Otic Solution, USP is a solution containing hydrocortisone (1%) and acetic acid (2%), in a propylene glycol vehicle containing benzethonium chloride (0.02%), citric acid (0.05%), propylene glycol diacetate (3%) and sodium acetate (0.015%). The empirical formulas for acetic acid and hydrocortisone are CH_3COOH, and $C_{21}H_{30}O_5$, with a molecular weight of 60.05 and 362.46, respectively. The structural formulas are:



Acetic Acid



Chemically, hydrocortisone is:
Pregn-4-ene-3, 20-dione,
11, 17, 21-trihydroxy-, (11β)–.

Hydrocortisone and 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; hydrocortisone is antiinflammatory, 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 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 and Acetic Acid to contact infected surfaces directly. To promote continuous contact, insert a wick of cotton saturated with Hydrocortisone and 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 Hydrocortisone and 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 Hydrocortisone and 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

Hydrocortisone and Acetic Acid Otic Solution, USP, containing hydrocortisone (1%) and acetic acid (2%), is available in 10 mL, measured-drop, safety-tip plastic bottles (NDC 50383-901-10).

STORAGE

Store at room temperature, 20° to 25°C (68° to 77°F).

Keep container tightly closed.

Rx only

Distributed by:

Akorn Operating Company LLC

Gurnee, IL 60031

Rev. 901:04 07/22

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

AKORN

NDC 50383-901-10

Hydrocortisone and Acetic Acid Otic Solution, USP

10 mL

Rx only

HYDROCORTISONE AND ACETIC ACID

hydrocortisone and acetic acid solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:50383-901
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	20.75 mg in 1 mL
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	10.375 mg in 1 mL

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:50383-901-10	1 in 1 CARTON	06/04/2009	
1		10 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA012770	06/04/2009	

Labeler - Akorn Operating Company LLC (117696873)

Registrant - Akorn Operating Company LLC (117693100)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn Operating Company LLC		117696873	MANUFACTURE(50383-901)