

HYDROCORTISONE AND ACETIC ACID- hydrocortisone and acetic acid solution

Cosette Pharmaceuticals, Inc.

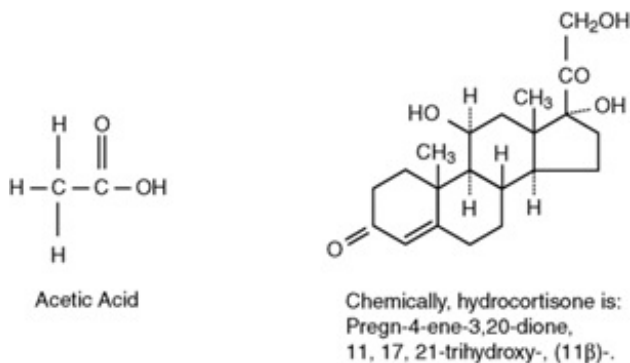
Hydrocortisone and Acetic Acid Otic Solution, USP

Rx only

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 (0.0025%). The empirical formulas for acetic acid and hydrocortisone are CH_3COOH , and $\text{C}_{21}\text{H}_{30}\text{O}_5$, with a molecular weight of 60.05 and 362.46, respectively.

The structural formulas are:



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 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 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.

To report SUSPECTED ADVERSE REACTIONS, contact Cosette Pharmaceuticals, Inc. at 1-800-922-1038 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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 0713-0849-09).

STORAGE

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

Rx only

Distributed by:

Cosette Pharmaceuticals, Inc.
South Plainfield, NJ 07080

Rev. 12/2023
8-0849CPLNC1
VC7758

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

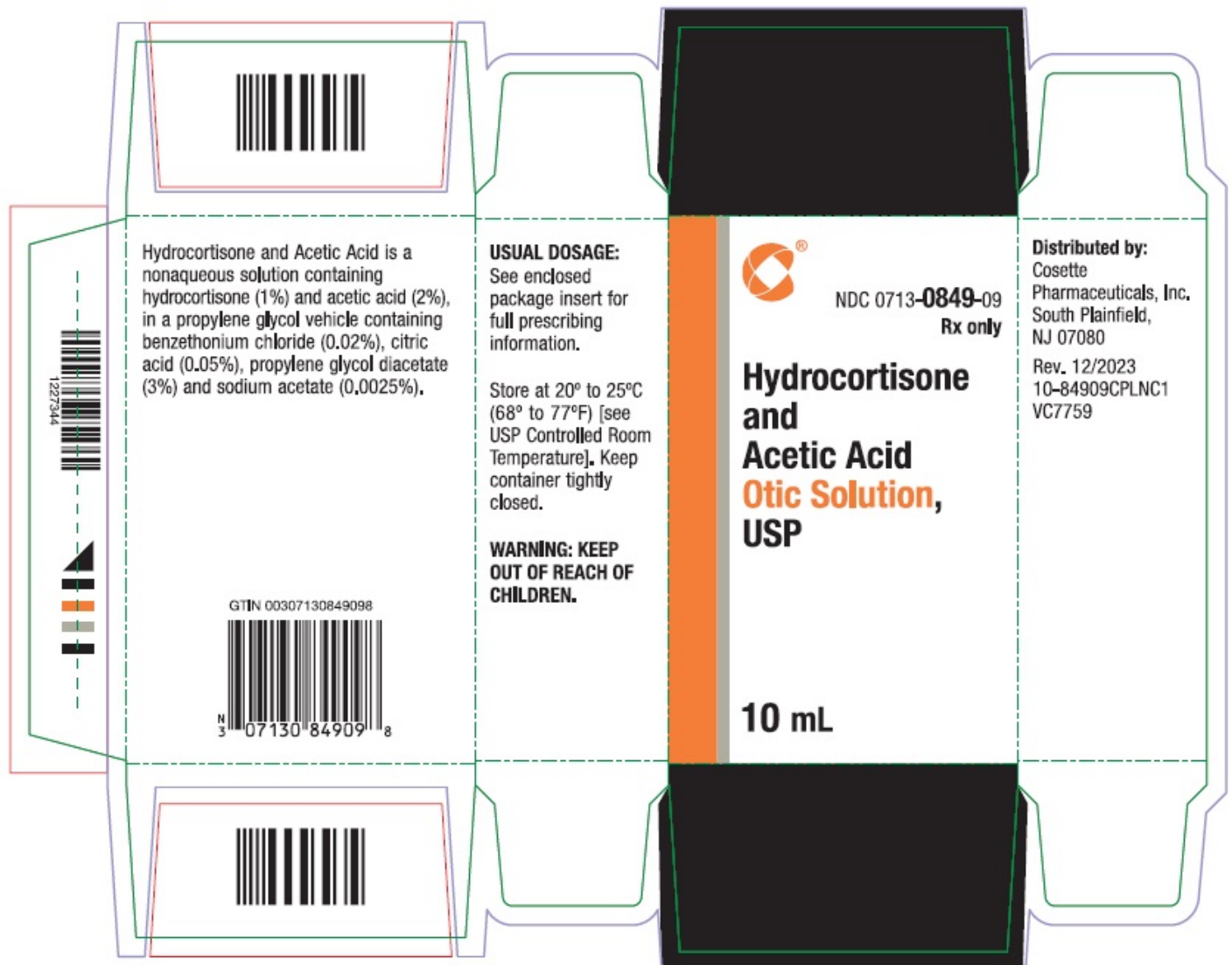
NDC 0713- **0849**-09

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Hydrocortisone and Acetic Acid Otic Solution, USP

10 mL

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HYDROCORTISONE AND ACETIC ACID

hydrocortisone and acetic acid solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0713-0849
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
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	10 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:0713-0849-09	1 in 1 CARTON	02/01/2024	
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	ANDA040609	02/01/2024	

Labeler - Cosette Pharmaceuticals, Inc. (116918230)

Registrant - Cosette Pharmaceuticals, Inc. (116918230)

Establishment

Name	Address	ID/FEI	Business Operations
Cosette Pharmaceuticals NC Laboratories, LLC		079419931	analysis(0713-0849) , label(0713-0849) , manufacture(0713-0849) , pack(0713-0849)

Revised: 2/2024

Cosette Pharmaceuticals, Inc.