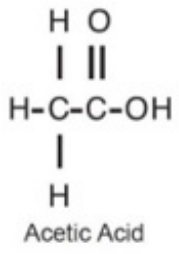
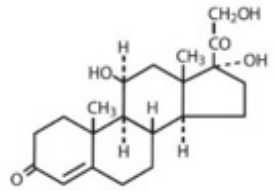
HYDROCORTISONE AND ACETIC ACID- hydrocortisone and acetic acid otic solution
Saptalis Pharmaceuticals, LLC

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 (0.015%). 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.

To report SUSPECTED ADVERSE REACTIONS, contact Saptalis Pharmaceuticals, LLC at 1-833-727-8254 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 71656-064-10).

STORAGE: Store at room temperature, 20° to 25°C (68° to 77°F). Keep container tightly closed.

Rx only

Distributed by:
Saptalis Pharmaceuticals, LLC
Hauppauge, NY 11788

MADE IN USA

January 2024-R2
PPM-0082

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

NDC 71656-064-10

Hydrocortisone and Acetic Acid Otic Solution, USP

1% / 2%

For Otic Use Only

Rx only

10 mL

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NDC 71656-064-10

Hydrocortisone and Acetic Acid Otic Solution, USP

1% / 2%

For Otic Use Only.

Rx only

10 mL

HYDROCORTISONE AND ACETIC ACID

hydrocortisone and acetic acid otic solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:71656-064
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:71656-064-10	1 in 1 CARTON	01/16/2024	
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	01/16/2024	

Labeler - Saptalis Pharmaceuticals, LLC (080145868)

Registrant - Saptalis Pharmaceuticals, LLC (080145868)

Establishment

Name	Address	ID/FEI	Business Operations
Saptalis Pharmaceuticals, LLC		081154447	manufacture(71656-064)

Revised: 1/2024 Saptalis Pharmaceuticals, LLC