

## DISCLAIMER

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## Hydrocortisone and Acetic Acid Otic Solution, USP

Rev. 901:01

5/09

**Rx only**

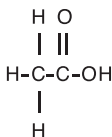
## Hydrocortisone and Acetic Acid Otic Solution, USP

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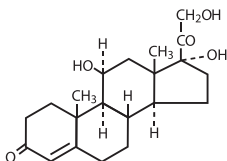
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**DESCRIPTION:** Hydrocortisone and Acetic Acid Otic Solution, USP is a solution containing hydrocortisone (1%) and acetic acid (2%), in a propylene glycol vehicle containing propylene glycol diacetate (3%), benzethonium chloride (0.02%), sodium acetate (0.015%) and citric acid (0.05%). The empirical formulas for acetic acid and hydrocortisone are  $\text{CH}_3\text{COOH}$ , 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:



Acetic Acid



Chemically, hydrocortisone is:  
Pregn-4-ene-3, 20-dione,  
11, 17, 21-trihydroxy-, (11 $\beta$ )-.

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.

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**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°- 25°C (68°-77°F). Keep container tightly closed.

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Hi-Tech Pharmacal Co., Inc.  
Amityville, NY 11701

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