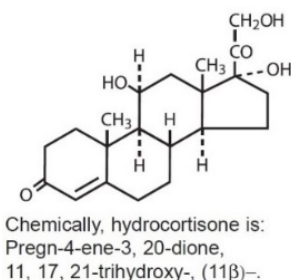
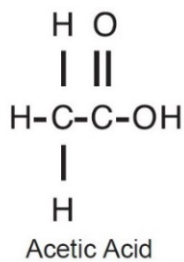


Hydrocortisone and Acetic Acid Otic Solution, USP

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 $\text{C}_{21}\text{H}_{30}\text{O}_5$, 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 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°C to 25°C (68°F to 77°F). Keep container tightly closed.

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Distributed by:

Saptalis Pharmaceuticals, LLC.

Hauppauge, NY 11788

MADE IN USA

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