

FORM 0882

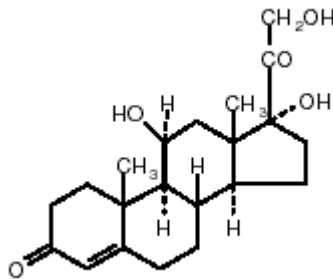
VC2767

Rev. 2/06

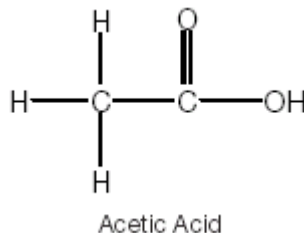
## HYDROCORTISONE AND ACETIC ACID OTIC SOLUTION USP

### DESCRIPTION

Hydrocortisone and Acetic Acid Otic Solution USP, is a solution containing hydrocortisone (1%) and acetic acid (2%), in a propylene glycol vehicle containing propylene glycol diacetate (3%), benzethonium chloride (0.02%), sodium acetate (0.015%), and citric acid (0.2%). The molecular formulas for acetic acid and hydrocortisone are  $C_2H_4O_2$  and  $C_{21}H_{30}O_5$ , with molecular weights of 60.05 and 362.46, respectively. The structural formulas are:



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



This product is available as a nonaqueous otic solution buffered at pH 2 to 4 for use in the external ear canal.

### CLINICAL PHARMACOLOGY

Acetic acid is anti-bacterial and anti-fungal; hydrocortisone is anti-inflammatory, anti-allergic and anti-pruritic; 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 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 solution to contact infected surfaces directly. To promote continuous contact, insert a wick of cotton saturated with the solution 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 solution every 4 to 6 hours. The wick may be removed after 24 hours but the patient should continue to instill 5 drops of solution 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, 1%/2% is available in a 10 mL measured-drop, safety-tip plastic bottle.

Store at controlled room temperature 20°-25°C (68°-77°F).

Keep container tightly closed.

Manufactured by:

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Baltimore, MD 21244 USA

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