

NOV 19 1997



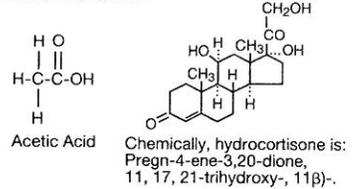
VōSoL[®] HC
OTIC SOLUTION
(hydrocortisone and acetic acid otic solution, USP)



IN-056H9-04D

Rev. 8/97

DESCRIPTION: VōSoL HC (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 CH₃COOH and C₂₁H₃₀O₅, with a molecular weight of 60.05 and 362.46, respectively. The structural formulas are:



VōSoL HC 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 VōSoL HC 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.

VōSoL[®] HC
OTIC SOLUTION

(hydrocortisone and acetic acid otic solution, USP)

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 VōSoL HC to contact infected surfaces directly. To promote continuous contact, insert a wick of cotton saturated with VōSoL HC 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 VōSoL HC every 4 to 6 hours. The wick may be removed after 24 hours but the patient should continue to instill 5 drops of VōSoL HC 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: VōSoL HC (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 0037-3811-12).

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

WALLACE LABORATORIES
Division of CARTER-WALLACE, INC.
Cranbury, New Jersey 08512

IN-056H9-04D

Rev. 8/97