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Acetic Acid Otic Solution, USP

Rev. 889:02 11/09

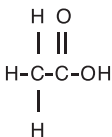
Rx only

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DESCRIPTION: Acetic Acid Otic Solution, USP is a solution of acetic acid (2%) in a propylene glycol vehicle containing propylene glycol diacetate (3%), benzethonium chloride (0.02%), and sodium acetate (0.015%). The empirical formula for acetic acid is CH_3COOH , with a molecular weight of 60.05. The structural formula is:



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; 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.

CONTRAINDICATIONS: Hypersensitivity to acetic acid or any of the ingredients. 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.

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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 acetic acid to contact infected surfaces directly. To promote continuous contact, insert a wick of cotton saturated with 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 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 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: Acetic Acid Otic Solution, USP, containing 2% acetic acid, is available in 15 mL (NDC 50383-889-15) measured-drop, safety-tip plastic bottles.

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

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