

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

40168

DRAFT FINAL PRINTED LABELING

**HYDROCORTISONE AND
ACETIC ACID OTIC
SOLUTION USP,
1%/2%**

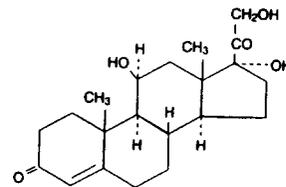
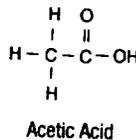
AUG 30 1996

APPROVED

DESCRIPTION

Hydrocortisone and Acetic Acid Otic Solution, USP is a nonaqueous solution containing Hydrocortisone, USP (1%) and Glacial Acetic Acid, USP (2%); in a propylene glycol vehicle containing benzethonium chloride, USP (0.02%); citric acid, USP (0.2%); propylene glycol diacetate, NF (3%) and sodium acetate, USP (0.015%).

The molecular 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 362.47, respectively. The structural formulas are:



Hydrocortisone and Acetic Acid Otic Solution, USP is available as a nonaqueous otic solution buffered at pH 3 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 Hydrocortisone and Acetic Acid Otic Solution 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.

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 Otic Solution to contact infected surfaces directly. To promote continuous contact, insert a wick saturated with Hydrocortisone and Acetic Acid Otic 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 Hydrocortisone and Acetic Acid Otic Solution 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 Otic Solution 3 or 4 times daily thereafter, for as long as indicated.

HOW SUPPLIED

Hydrocortisone and Acetic Acid Otic Solution USP, 1%/2% is supplied in 10 mL measured-drop, safety-tip plastic bottles.

STORAGE

Store at controlled room temperature, 15 °-30 °C (59 °-86 °F).

KEEP CONTAINER TIGHTLY CLOSED

CAUTION: Federal law prohibits dispensing without prescription.

Product No.: 8740

Manufactured By:
Morton Grove Pharmaceuticals, Inc.
Morton Grove, IL 60053

28740
ISS. 5-96

**HYDROCORTISONE AND ACETIC ACID OTIC
SOLUTION USP, 1%/2%
PRODUCT CODE 8740
FINAL PRINTED 10-mL CONTAINER LABELING**

Hydrocortisone and Acetic Acid Otic Solution,
USP is a nonaqueous solution containing 1%
hydrocortisone and 2% acetic acid in a
propylene glycol vehicle containing benzocaine,
sodium chloride, USP, citric acid, USP, propylene
glycol diacetate, NF and sodium acetate, USP.

3 60432-740-01 2

MGP
NDC 60432-740-01
**HYDROCORTISONE
AND ACETIC ACID
OTIC SOLUTION USP,
1%/2%**
CAUTION: Federal law prohibits
dispensing without prescription.
NET CONTENTS: 10 mL

DO NOT USE IF BAND PRINTED "SEALED FOR YOUR
PROTECTION" SHOWS CAPS DAMAGED OR MISSING.
USUAL DOSAGE: See package insert for full
directions for use.
Store at controlled room temperature,
15°-30° C (59°-86° F).
KEEP CONTAINER TIGHTLY CLOSED
Manufactured by:
Morton Grove Pharmaceuticals, Inc.
Morton Grove, IL 60053
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