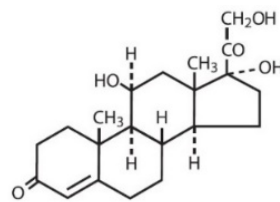
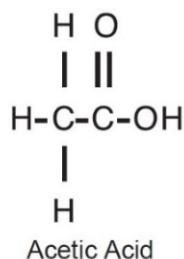


# Hydrocortisone and Acetic Acid Otic Solution, USP

## 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  $\text{CH}_3\text{COOH}$ , 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:



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

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](http://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.

**Rx only**

Distributed by:

**Saptalis Pharmaceuticals, LLC.**

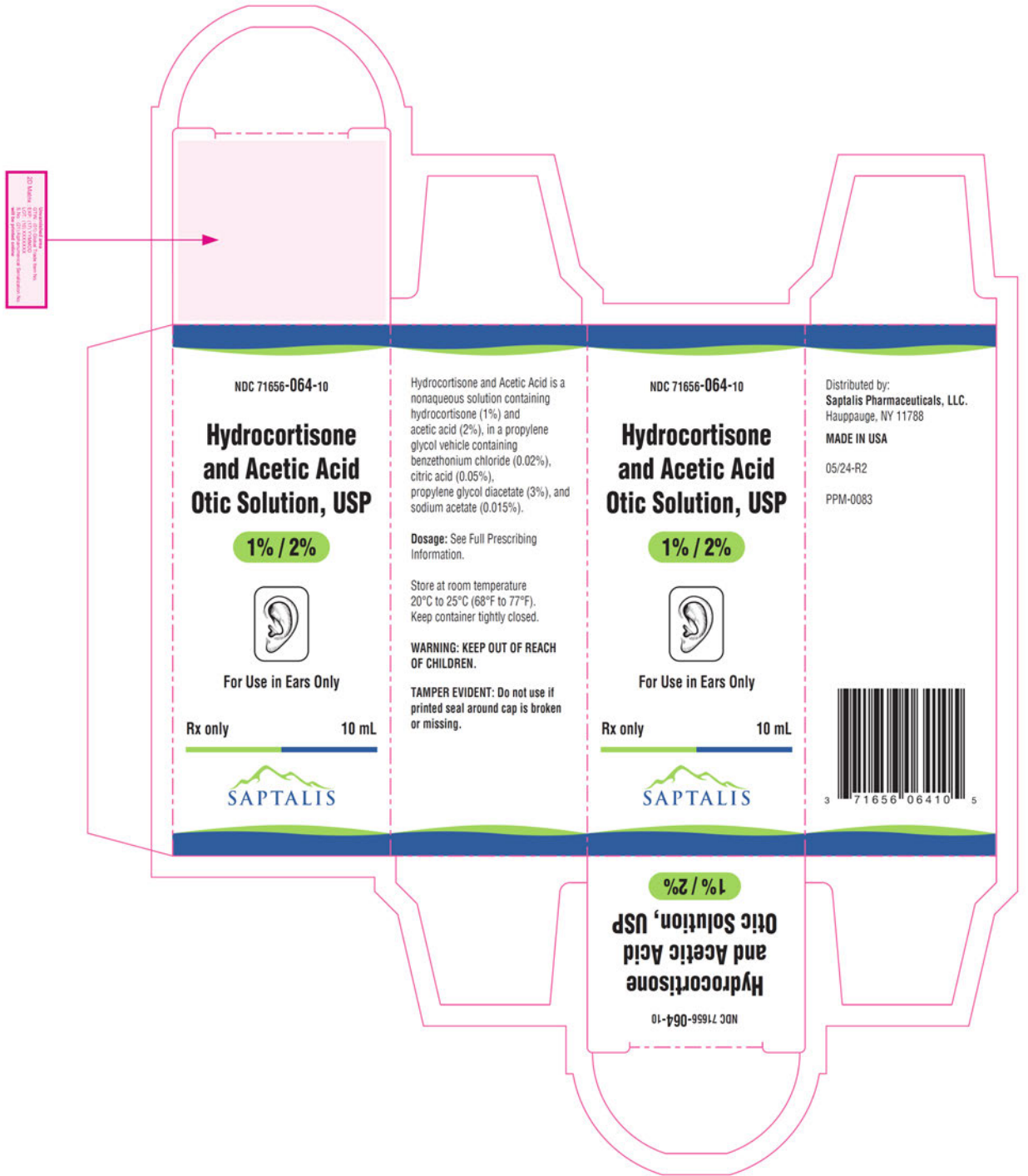
Hauppauge, NY 11788

**MADE IN USA**

MAY 2024-R3

PPM-0082

# Carton Labeling



# Container Label

NDC 71656-064-10

## Hydrocortisone and Acetic Acid Otic Solution, USP

**1% / 2%**



For Use in Ears Only

Rx only 10 mL

Hydrocortisone and Acetic Acid is a nonaqueous 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%).

**Dosage:** See Full Prescribing Information.

Store at room temperature 20°C to 25°C (68°F to 77°F). Keep container tightly closed.

**WARNING: KEEP OUT OF REACH OF CHILDREN.**

**TAMPER EVIDENT: Do not use if printed seal around cap is broken or missing.**

Distributed by:  
**Saptalis Pharmaceuticals, LLC.**  
Hauppauge, NY 11788

**MADE IN USA**



05/24-R3



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LAM-0050

**UNVARNISHED AREA**

Unvarnished area for batch details  
LOT.: XXXXXX  
EXP.: MM/YYYY  
will be printed online

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**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**  
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/s/  
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WILLIAM M BOYD  
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