**HYDROCORTISONE AND ACETIC ACID- hydrocortisone and acetic acid solution**
**Taro Pharmaceuticals U.S.A., Inc.**

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**Hydrocortisone 1%**
**and Acetic Acid 2%**
**Otic Solution**

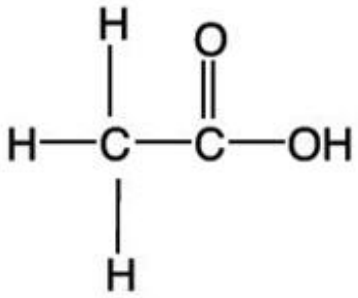
**(Hydrocortisone and Acetic Acid Otic Solution, USP)**

**Rx only**

## DESCRIPTION

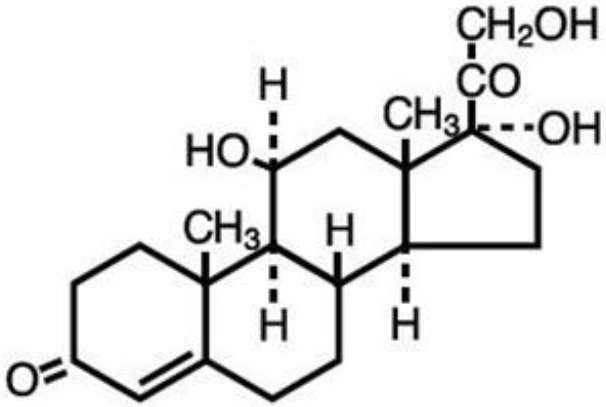
Hydrocortisone and Acetic Acid Otic Solution, USP contains Hydrocortisone (1%) and acetic acid, glacial (2%) in a propylene glycol vehicle containing benzethonium chloride (0.02%), citric acid (0.2%), propylene glycol diacetate (3%) and sodium acetate (0.015%).

Acetic acid has a molecular formula of $CH_3COOH$ with molecular weight of 60.05. The structural formula is:




**Acetic Acid**

Hydrocortisone is a Synthetic Steroid used as an anti-inflammatory and antipruritic agent. Its chemical name is Pregn-4-ene-3,20-dione, 11, 17, 21-trihydroxy-, (11β)-. Hydrocortisone has a molecular formula of $C_{21}H_{30}O_5$ with molecular weight 362.46. The structural formula is:




**Hydrocortisone**

Hydrocortisone and acetic acid is available as a non-aqueous otic solution buffered at pH (2.0 to 4.0)

for use in the external ear canal.

## CLINICAL PHARMACOLOGY

Acetic acid is anti-bacterial and antifungal; hydrocortisone is anti-inflammatory, 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 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.

### 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 hydrocortisone 1% and acetic acid 2% otic 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 the solution every 4 to 6 hours. The wick may be removed after 24 hours but the patient should continue to instill 5 drops 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 1% and acetic acid 2% otic solution is available in 10 mL plastic, controlled dropper tip bottle.

| | |
|---|---|
| 10 mL bottle | NDC 51672-3007-1 |

**Store at 20° to 25°C (68° to 77°F)** [see USP Controlled Room Temperature]. Protect from freezing. Keep container tightly closed.

Mfd. by: Taro Pharmaceuticals Inc.
Brampton, Ontario, Canada L6T 1C1
Dist. by: **Taro Pharmaceuticals U.S.A., Inc.**
Hawthorne, NY 10532

Revised: May, 2015

PK-4785-1
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0515-1

**PRINCIPAL DISPLAY PANEL - 10 mL Bottle Carton**

**10 mL**

**NDC 51672-3007-1**

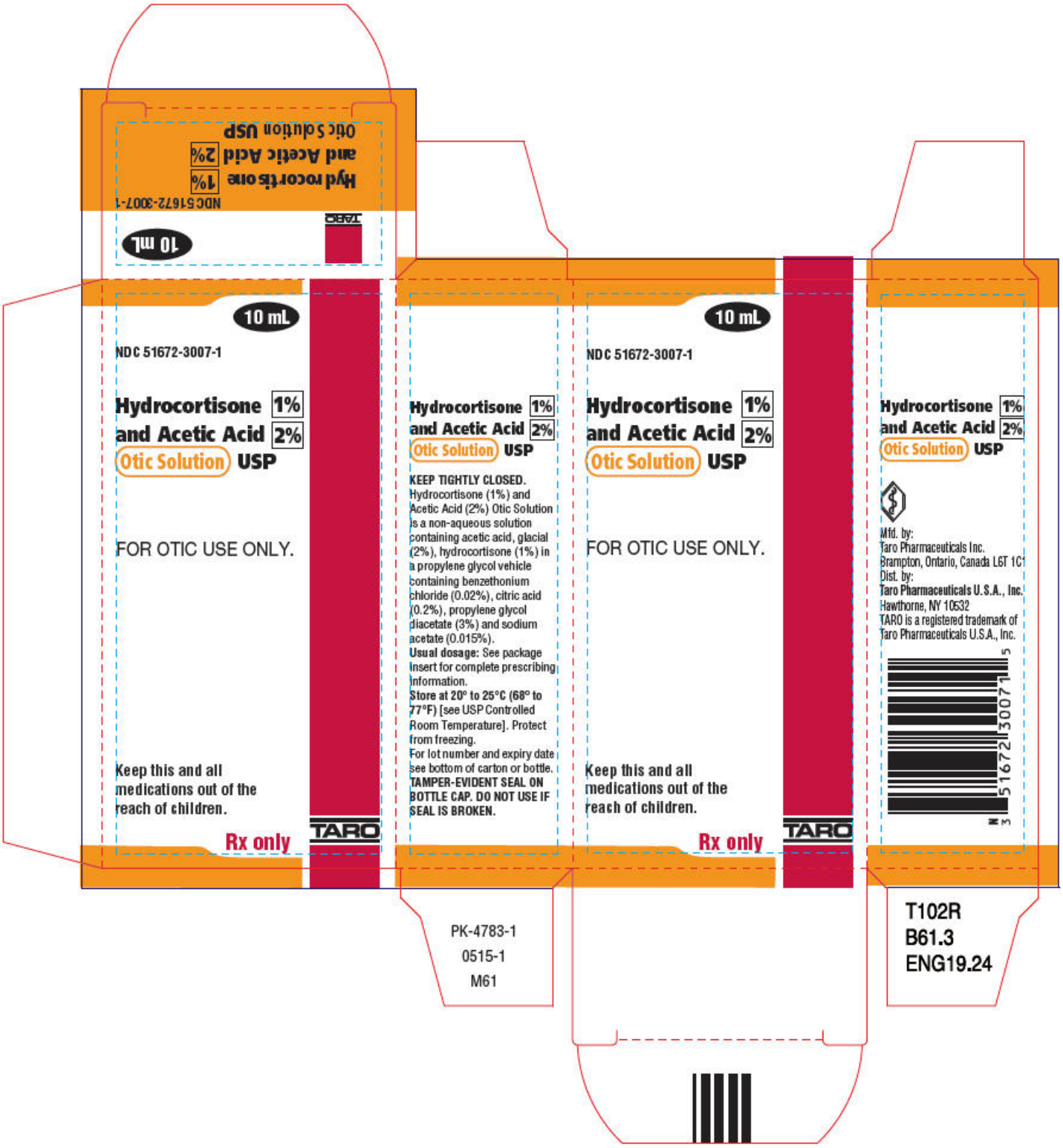
**Hydrocortisone 1%
and Acetic Acid 2%
Otic Solution USP**

FOR OTIC USE ONLY.

**Keep this and all
medications out of the
reach of children.**

**Rx only**

**TARO**




# HYDROCORTISONE AND ACETIC ACID

hydrocortisone and acetic acid solution

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:51672-3007 |
| **Route of Administration** | AURICULAR (OTIC) | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **Hydrocortisone** (UNII: WI4X0X7BPJ) (Hydrocortisone - UNII:WI4X0X7BPJ) | Hydrocortisone | 10.4 mg in 1 mL |
| **Acetic Acid** (UNII: Q40Q9N063P) (Acetic Acid - UNII:Q40Q9N063P) | Acetic Acid | 20.8 mg in 1 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **propylene glycol** (UNII: 6DC9Q167V3) | |
| **propylene glycol diacetate** (UNII: 5Z492UNF9O) | |
| **benzethonium chloride** (UNII: PH41D05744) | |
| **sodium acetate** (UNII: 4550K0SC9B) | |
| **anhydrous citric acid** (UNII: XF417D3PSL) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:51672-3007-1 | 1 in 1 CARTON | 04/28/2005 | |
| **1** | | 10 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA088759 | 04/28/2005 | |

## Labeler - Taro Pharmaceuticals U.S.A., Inc. (145186370)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Taro Pharmaceuticals Inc. | | 206263295 | MANUFACTURE(51672-3007) |

Revised: 12/2019 Taro Pharmaceuticals U.S.A., Inc.