Anti-Itch Cream 2% Diphenhydramine Hydrochloride

Drug Facts

<table>
<thead>
<tr>
<th>Active ingredients</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diphenhydramine hydrochloride 2%</td>
<td>Topical analgesic</td>
</tr>
<tr>
<td>Zinc acetate 0.1%</td>
<td>Skin protectant</td>
</tr>
</tbody>
</table>

**Uses**
- temporarily relieves pain and itching associated with:
  - insect bites
  - minor burns
  - sunburn
  - minor skin irritations
  - minor cuts
  - scrapes
  - rashes due to poison ivy, poison oak, and poison sumac
- dries the oozing and weeping of poison ivy, poison oak, and poison sumac

**Warnings**

*For external use only*

**Do not use**
- on large areas of the body
- with any other product containing diphenhydramine, even one taken by mouth

**Ask a doctor before use**
- on chicken pox
- on measles

**When using this product**
- avoid contact with eyes

**Stop use and ask a doctor if**
- condition worsens or does not improve within 7 days
- symptoms persist for more than 7 days or clear up and occur again within a few days

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**
- do not use more often than directed
adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily
children under 2 years of age: ask a doctor

Other information
- To open: unscrew cap, use pointed end of cap to puncture seal.
- store at 20° to 25°C (68° to 77°F)
- see carton or tube crimp for lot number and expiration date

Inactive ingredients
- cetyl alcohol, glyceryl stearate, glyceryl stearate/PEG-100 stearate, methylparaben, propylene glycol, propylparaben and purified water

Questions?
Call 1-866-923-4914

Distributed by:
Taro Pharmaceuticals
U.S.A., Inc.
Hawthorne, NY 10532

PRINCIPAL DISPLAY PANEL - 28.4 g Tube Carton
Extra Strength
Anti-Itch Cream
Diphenhydramine Hydrochloride 2%
and Zinc Acetate 0.1%
Topical Analgesic • Skin Protectant
NET WT 1 oz (28.4 g)
Anti-Itch Cream
Diphenhydramine Hydrochloride 2%
and Zinc Acetate 0.1%
Topical Analgesic • Skin Protectant

Relieves pain and itch from insect bites,
minor skin irritations and rashes due to
poison ivy, poison oak and poison sumac

NET WT 1 oz (28.4 g)

Distributed by:
Taro Pharmaceuticals U.S.A., Inc.
Hawthorne, NY 10532
Taro is a registered trademark of Taro Pharmaceuticals U.S.A., Inc.
Made in Canada

Drug Facts (continued)
Extra Strength
# DIPHENHYDRAMINE HYDROCHLORIDE AND ZINC ACETATE

**diphenhydramine hydrochloride and zinc acetate cream**

## Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
<th>NDC:51672-2089</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUMAN OTC DRUG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TOPICAL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diphenhydramine Hydrochloride</td>
<td>Diphenhydramine Hydrochloride</td>
<td>20 mg in 1 g</td>
</tr>
<tr>
<td>Zinc Acetate</td>
<td>Zinc Acetate</td>
<td>1 mg in 1 g</td>
</tr>
</tbody>
</table>

## Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cetyl alcohol</td>
<td></td>
</tr>
<tr>
<td>Glyceryl monostearate</td>
<td></td>
</tr>
<tr>
<td>PEG-100 stearate</td>
<td></td>
</tr>
<tr>
<td>Methylparaben</td>
<td></td>
</tr>
<tr>
<td>Propylene glycol</td>
<td></td>
</tr>
<tr>
<td>Propylparaben</td>
<td></td>
</tr>
<tr>
<td>Water</td>
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</table>

## Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:51672-2089-2</td>
<td>1 in 1 CARTON</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>28.4 g in 1 TUBE</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tbody>
<tr>
<td>OTC MONOGRAPH NOT FINAL</td>
<td>part348</td>
<td>09/20/2005</td>
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</tbody>
</table>

## Labeler

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

## Establishment

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Taro Pharmaceutical Inc.</td>
<td></td>
<td>206263295</td>
<td>MANUFACTURE(51672-2089)</td>
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</tbody>
</table>

Revised: 7/2014