DIPHENHYDRAMINE - diphenhydramine hydrochloride tablet, coated
New World Imports, Inc

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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Drug Facts

Diphenhydramine HCL 25mg
Antihistamine

In case of accidental overdose, contact a doctor or Poison Control Center immediately.
Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
Sneezing, runny nose, itchy / watery eyes, and itching of the nose or throat
Temporarily relieves these symptoms associated with the common cold:
Sneezing, runny nose

Do not use with any other products containing diphenhydramine, including one applied topically

Ask a doctor before use if you have:
A breathing problem such as emphysema or chronic bronchitis
Glaucoma
Trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product:
Marked drowsiness may occur
Avoid alcoholic beverages
Alcohol, sedatives, and tranquilizers may increase drowsiness
Be careful when driving a motor vehicle or operating machinery
Excitability may occur, especially in children

If pregnant or breast-feeding, ask a health professional before use

Take every 4 to 6 hours
Do not take more than 6 doses in 24 hours
Adults and children 12 years of age and older; 1 to 2 caplets
Children 6 to 12 years: 1 caplet
Children under 6: Consult a doctor

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DIPHENHYDRAMINE
diphenhydramine hydrochloride tablet, coated

Product Information

Product Type: HUMAN OTC DRUG
Route of Administration: ORAL

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 (UNII: TC2D6JDAD40)</td>
<td>Diphenhydramine Hydrochloride</td>
<td>25 mg</td>
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</tbody>
</table>

Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)</td>
<td></td>
</tr>
<tr>
<td>D&amp;C RED NO. 27 (UNII: 2LRS185U6K)</td>
<td></td>
</tr>
<tr>
<td>HYDROXYMETHYL CELLULOSE (UNII: 273FM27VK1)</td>
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</tbody>
</table>
**Product Characteristics**

<table>
<thead>
<tr>
<th>Color</th>
<th>Score</th>
<th>Shape</th>
<th>Size</th>
<th>Imprint Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>pink (Bright Pink)</td>
<td>no score</td>
<td>OVAL (Oval in Shape, sides straight, top and bottom rounded)</td>
<td>11mm</td>
<td>048;D</td>
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**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>
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<td>NDC:51824-048-01</td>
<td>100 in 1 BOTTLE; Type 0: Not a Combination Product</td>
<td>09/09/2010</td>
<td>08/01/2020</td>
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**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 final</td>
<td>part341</td>
<td>09/09/2010</td>
<td>08/01/2020</td>
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</tbody>
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**Labeler** - New World Imports, Inc (075372276)

Revised: 8/2017

New World Imports, Inc