CETIRIZINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE-
cetirizine hcl, pseudoephedrine hcl tablet, extended release
Perrigo New York Inc

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Perrigo Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride Drug Facts

Active ingredients (in each extended release tablet)
Cetirizine HCl 5 mg
Pseudoephedrine HCl 120 mg

Purpose
Antihistamine
Nasal Decongestant

Uses
• temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
  • runny nose
  • sneezing
  • itchy, watery eyes
  • itching of the nose or throat
  • nasal congestion
  • reduces swelling of nasal passages
  • temporarily relieves sinus congestion and pressure
  • temporarily restores freer breathing through the nose

Warnings

Do not use
• if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine.
• if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson’s disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have
• heart disease
• thyroid disease
• diabetes
• glaucoma
• high blood pressure
• trouble urinating due to an enlarged prostate gland
• liver or kidney disease. Your doctor should determine if you need a different dose.

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

When using this product

• do not use more than directed
• drowsiness may occur
• avoid alcoholic drinks
• alcohol, sedatives, and tranquilizers may increase drowsiness
• be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

• an allergic reaction to this product occurs. Seek medical help right away.
• you get nervous, dizzy, or sleepless
• symptoms do not improve within 7 days or are accompanied by fever

If pregnant or breast-feeding:

• if breast-feeding: not recommended
• if pregnant: ask a health professional before use.

Keep out of reach of children.
In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

• do not break or chew tablet; swallow tablet whole

<table>
<thead>
<tr>
<th>Adults and children 12 years and over</th>
<th>take 1 tablet every 12 hours; do not take more than 2 tablets in 24 hours.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults 65 years and over</td>
<td>ask a doctor</td>
</tr>
<tr>
<td>Children under 12 years of age</td>
<td>ask a doctor</td>
</tr>
<tr>
<td>Consumers with liver or kidney disease</td>
<td>ask a doctor</td>
</tr>
</tbody>
</table>

Other information

• store between 20° to 25°C (68° to 77°F)

Inactive ingredients
colloidal silicon dioxide, hydroxypropyl cellulose, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, talc, yellow iron oxide

Questions or comments?
Principal Display Panel
Compare to Zyrtec-D® active ingredients
Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride
Extended Release Tablets
5 mg/120 mg
Antihistamine / Nasal Decongestant
12 Hour Relief of:
Sneezing
Itchy, Watery Eyes
Runny Nose
Itchy Throat or Nose
Sinus Pressure
Nasal Congestion
actual size
Original Prescription Strength
Indoor & Outdoor Allergies
12 Extended Release Tablets
Allergy & Congestion
### Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
<th>NDC:45802-721</th>
</tr>
</thead>
<tbody>
<tr>
<td>Route of Administration</td>
<td>ROUTAL</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>CETIRIZINE HYDROCHLORIDE (UNII: 640047KTOA) (CETIRIZINE - UNII:YO7261ME24)</td>
<td>CETIRIZINE HYDROCHLORIDE</td>
<td>5 mg</td>
</tr>
<tr>
<td>PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)</td>
<td>PSEUDOEPHEDRINE HYDROCHLORIDE</td>
<td>120 mg</td>
</tr>
</tbody>
</table>

### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>SILICON DIOXIDE (UNII: ETJ7Z6XBU4)</td>
<td></td>
</tr>
<tr>
<td>HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N60H)</td>
<td></td>
</tr>
<tr>
<td>HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)</td>
<td></td>
</tr>
<tr>
<td>LACTOSE MONOHYDRATE (UNII: EWQ57Q8J5X)</td>
<td></td>
</tr>
<tr>
<td>MAGNESIUM STEARATE (UNII: 70097M6B0)</td>
<td></td>
</tr>
<tr>
<td>MICROCRYSTALLINE CELLULOSE (UNII: OPIR32D61U)</td>
<td></td>
</tr>
<tr>
<td>TALC (UNII: 7SEV7J4R1U)</td>
<td></td>
</tr>
<tr>
<td>FERRIC OXIDE YELLOW (UNII: EX43802MRT)</td>
<td></td>
</tr>
</tbody>
</table>

### Product Characteristics

<table>
<thead>
<tr>
<th>Color</th>
<th>Score</th>
<th>Size</th>
<th>Imprint Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>WHITE (one side white one side light yellow)</td>
<td>no score</td>
<td>12mm</td>
<td>5029;5;120</td>
</tr>
<tr>
<td>Shape</td>
<td>ROUND</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flavor</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contains</td>
<td></td>
<td></td>
<td></td>
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</tbody>
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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>
<td>1</td>
<td>NDC:45802-721-62</td>
<td>24 in 1 CARTON</td>
<td>04/10/2008</td>
<td></td>
</tr>
</tbody>
</table>
1 in 1 BLISTER PACK; Type 0: Not a Combination Product

NDC:45802-721-53  12 in 1 CARTON  05/16/2014

1 in 1 BLISTER PACK; Type 0: Not a Combination Product

**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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</thead>
<tbody>
<tr>
<td>ANDA</td>
<td>ANDA077170</td>
<td>04/10/2008</td>
<td></td>
</tr>
</tbody>
</table>

**Labeler** - Perrigo New York Inc (078846912)

Revised: 12/2019

Perrigo New York Inc