ZYRTEC D ALLERGY AND CONGESTION - cetirizine hydrochloride and pseudoephedrine hydrochloride tablet, extended release
Physicians Total Care, Inc.

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ZYRTEC-D®

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. (1-800-222-1222)

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)
- do not use if individual blister unit is open or torn
- see back panel for lot number and expiration date

Inactive ingredients
- colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide

Questions?
call 1-800-343-7805

PRINCIPAL DISPLAY PANEL
NDC 54868-5879-0
Original Prescription Strength
ZYRTEC-D®
Cetirizine HCl 5 mg/antihistamine
Pseudoephedrine HCl 120 mg/nasal decongestant
Extended Release Tablets

Indoor & Outdoor Allergies
ALLERGY & CONGESTION
12 hour

Relief of
• Sneezing
• Runny Nose
• Sinus Pressure

• Itchy, Watery Eyes
• Itchy Throat or Nose
• Nasal Congestion

24 Extended Release Tablets (individual Blisters)

ZYRTEC D ALLERGY AND CONGESTION
cetirizine hydrochloride and pseudoephedrine hydrochloride tablet, extended release

Product Information
Product Type: HUMAN OTC DRUG
Item Code (Source): NDC:54868-5879(NDC:50580-728)
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>Cetirizine Hydrochloride (UNII: 64O047KTOA) (Cetirizine - UNII:YO7261ME24)</td>
<td>Cetirizine</td>
<td>5 mg</td>
</tr>
<tr>
<td>Pseudoephedrine Hydrochloride (UNII: 6V9V2RYJ8N) (Pseudoephedrine - UNII:7CUC9DD9F)</td>
<td>Pseudoephedrine</td>
<td>120 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>Ingredient</td>
<td>UNII Code</td>
</tr>
<tr>
<td>------------</td>
<td>-------------</td>
</tr>
<tr>
<td>Silicon Dioxide</td>
<td>ETJ7Z6XBU4</td>
</tr>
<tr>
<td>Croscarmellose Sodium</td>
<td>M280L1HH48</td>
</tr>
<tr>
<td>Hypromelloses</td>
<td>3NXW29V3WO</td>
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<tr>
<td>Lactose Monohydrate</td>
<td>EWQ57Q8I5X</td>
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<tr>
<td>Magnesium Stearate</td>
<td>70097M6I30</td>
</tr>
<tr>
<td>CellULOSE, MICROCRYSTALLINE</td>
<td>OP1R32D61U</td>
</tr>
<tr>
<td>Polyethylene Glycols</td>
<td>3WJQ0SDW1A</td>
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<tr>
<td>Titanium Dioxide</td>
<td>15FIX9V2JP</td>
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**Product Characteristics**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Description</th>
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<tbody>
<tr>
<td>Color</td>
<td>WHITE (White to off white)</td>
</tr>
<tr>
<td>Shape</td>
<td>ROUND (Biconvex)</td>
</tr>
<tr>
<td>Flavor</td>
<td>Imprint Code: Zyrtec:D</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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<tbody>
<tr>
<td>1</td>
<td>NDC:54868-5879-0</td>
<td>24 in 1 CARTON</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>1 in 1 BLISTER PACK</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>NDA</td>
<td>NDA021150</td>
<td>03/28/2008</td>
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**Labeler** - Physicians Total Care, Inc. (194123980)

**Establishment**

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
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</thead>
<tbody>
<tr>
<td>Physicians Total Care, Inc.</td>
<td></td>
<td>194123980</td>
<td>relabel</td>
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