12 HOUR ALLERGY D- cetirizine hcl, pseudoephedrine hcl tablet, extended release
Meijer Distribution Inc

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Meijer Distribution, Inc. 12 Hour Allergy-D Drug Facts

Active ingredient (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?
1-800-719-9260
Principal Display Panel

Compare to Zyrtec-D® active ingredients

ALLERGY & CONGESTION

12 Hour Allergy-D

Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride

Extended Release Tablets 5 mg/120 mg

antihistamine/nasal decongestant

Indoor & Outdoor Allergies

12 Hour Relief of:

Sneezing

Itchy, Watery Eyes

Runny Nose

Itchy Throat or Nose

Sinus Pressure

Nasal Congestion

Actual Size

Original Prescription Strength
Compare to Zyrtec-D® active ingredients

12 Hour Allergy-D
Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride Extended Release Tablets 5 mg/120 mg antihistamine/nasal decongestant

Indoor & Outdoor Allergies
12 Hour Relief of:
- Sneezing
- Itchy, Watery Eyes
- Runny Nose
- Itchy Throat or Nose
- Sinus Pressure
- Nasal Congestion

24 Extended Release Tablets

Original Prescription Strength
12 HOUR ALLERGY D
cetirizine hcl, pseudoephedrine hcl tablet, extended release

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>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:7CUC9DD9F)</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>HYPMELLOSES (UNII: 3NXW29V3WO)</td>
<td></td>
</tr>
</tbody>
</table>
## LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)

## MAGNESIUM STEARATE (UNII: 70097M6I30)

## CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)

## TALC (UNII: 7SEV7J4R1U)

## FERRIC OXIDE YELLOW (UNII: EX438O2MRT)

### Product Characteristics

<table>
<thead>
<tr>
<th>Color</th>
<th>Score</th>
<th>Shape</th>
<th>Size</th>
<th>Imprint Code</th>
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</thead>
<tbody>
<tr>
<td>WHITE (one side white one side light yellow)</td>
<td>no score</td>
<td>ROUND</td>
<td>12mm</td>
<td>5029;5;120</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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<tbody>
<tr>
<td>1</td>
<td>NDC:41250-299-53</td>
<td>2 in 1 CARTON</td>
<td>05/14/2008</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>6 in 1 BLISTER PACK; Type 0: Not a Combination Product</td>
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<td></td>
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<tr>
<td>2</td>
<td>NDC:41250-299-62</td>
<td>4 in 1 CARTON</td>
<td>05/14/2008</td>
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<td></td>
<td>6 in 1 BLISTER PACK; Type 0: Not a Combination Product</td>
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<td></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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<tr>
<td>ANDA</td>
<td>ANDA077170</td>
<td>07/15/1988</td>
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### Labeler

- Meijer Distribution Inc (006959555)

Revised: 12/2018