

**12 HOUR ALLERGY D- cetirizine hydrochloride, pseudoephedrine hydrochloride tablet, film coated, extended release**  
**Meijer Distribution Inc**

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**Meijer Distribution, Inc 12 Hour Allergy-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

adults and children 12 years and over	take 1 tablet every 12 hours; do not take more than 2 tablets in 24 hours.
adults 65 years and over	ask a doctor
children under 12 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

**Other information**

- store between 20° to 25°C (68° to 77°F)
- **do not use if blister unit is broken or torn**

- see side panel for lot number and expiration date
- meets USP *Dissolution Test 2*

**Inactive ingredients**

colloidal silicon dioxide, hypromellose, lactose monohydrate, low-substituted hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide

**Questions or comments?**

**1-800-719-9260**

**Package/Label Principal Display Panel**

Compare to Zyrtec-D<sup>®</sup> 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; Runny Nose; Sinus Pressure; Watery, Itchy Eyes; Itchy Throat or Nose; Nasal Congestion

ORIGINAL PRESCRIPTION STRENGTH

12 Extended-Release Tablets | actual size

ALLERGY & CONGESTION

# 12 hour allergy-D

Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablets, 5 mg/120 mg Antihistamine | Nasal Decongestant



**meijer**

NDC 41250-728-53

Compare to Zyrtec-D<sup>®</sup> 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:**

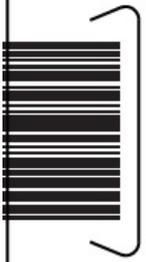
Sneezing; Runny Nose; Sinus Pressure; Itchy, Watery Eyes; Itchy Throat or Nose; Nasal Congestion

ORIGINAL  
PRESCRIPTION  
STRENGTH

**12 Extended-  
Release Tablets**



actual size



14753 8E C2

CODE AREA

<p><b>Drug Facts</b></p> <p><b>Active ingredients</b> <span style="float: right;"><b>Purpose</b></span>  <i>(in each extended release tablet)</i></p> <p>Cetirizine HCl 5 mg.....Antihistamine  Pseudoephedrine HCl 120 mg.....Nasal decongestant</p> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>■ temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: <ul style="list-style-type: none"> <li>■ runny nose</li> <li>■ sneezing</li> <li>■ itchy, watery eyes</li> <li>■ itching of the nose or throat</li> <li>■ nasal congestion</li> <li>■ redness/swelling of nasal passages</li> </ul> </li> <li>■ temporarily relieves sinus congestion and pressure</li> <li>■ temporarily relieves freer breathing through the nose</li> </ul> <p><b>Warnings</b></p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>■ if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine</li> <li>■ 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.</li> </ul> <p><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"> <li>■ heart disease</li> <li>■ thyroid disease</li> <li>■ diabetes</li> <li>■ glaucoma</li> <li>■ high blood pressure</li> <li>■ trouble urinating due to an enlarged prostate gland</li> <li>■ liver or kidney disease. Your doctor should determine if you need a different dose.</li> </ul>	<p><b>Drug Facts (continued)</b></p> <p><b>Ask a doctor or pharmacist before use if you are taking</b> tranquilizers or sedatives.</p> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>■ do not use more than directed</li> <li>■ drowsiness may occur</li> <li>■ avoid alcoholic drinks</li> <li>■ alcohol, sedatives, and tranquilizers may increase drowsiness</li> <li>■ be careful when driving a motor vehicle or operating machinery</li> </ul> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>■ an allergic reaction to this product occurs. Seek medical help right away.</li> <li>■ you get nervous, dizzy, or sleepless</li> <li>■ symptoms do not improve within 7 days or are accompanied by fever</li> </ul> <p><b>If pregnant or breast-feeding:</b></p> <ul style="list-style-type: none"> <li>■ if breast-feeding: not recommended</li> <li>■ if pregnant: ask a health professional before use.</li> </ul> <p><b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222)</p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>■ do not break or chew tablets; swallow tablet whole</li> </ul> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">adults and children 12 years and over</td> <td style="width: 50%;">take 1 tablet every 12 hours; do not take more than 2 tablets in 24 hours.</td> </tr> <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> </table>	adults and children 12 years and over	take 1 tablet every 12 hours; do not take more than 2 tablets in 24 hours.	adults 65 years and over	ask a doctor	children under 12 years of age	ask a doctor	consumers with liver or kidney disease	ask a doctor
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GRAND RAPIDS, MI 49544  
www.meijer.com

**Drug Facts (continued)**

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- do not use if blister unit is broken or torn
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**Inactive ingredients** colloidal silicon dioxide, hypromellose, lactose monohydrate, low-substituted hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide

**Questions or comments?** 1-800-719-9260

\*This product is not manufactured or distributed by UCB Biopharma SPRL, owner of the registered trademark Zyrtec-D®.

PD 525026

<b>12 HOUR ALLERGY D</b>			
cetirizine hydrochloride, pseudoephedrine hydrochloride tablet, film coated, extended release			
Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41250-728
<b>Route of Administration</b>	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	5 mg	
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg	
Inactive Ingredients			
Ingredient Name	Strength		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			
LACTOSE MONOHYDRATE (UNII: EWQ57Q815X)			
LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 2165RE0K14)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			

<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	L147
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-728-53	12 in 1 CARTON	04/07/2020	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:41250-728-62	24 in 1 CARTON	04/07/2020	
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210719	04/07/2020	

**Labeler** - Meijer Distribution Inc (006959555)

Revised: 9/2020

Meijer Distribution Inc