

**CHILDRENS CETIRIZINE HYDROCHLORIDE - cetirizine hydrochloride tablet,  
orally disintegrating  
WALGREEN CO.**

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***Drug Facts***

***Active ingredient (in each tablet)***

Cetirizine hydrochloride USP 10 mg

***Purpose***

Antihistamine

***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

***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.

**Ask a doctor before use if you have**

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**

- 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.

### **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**

Tablet melts in mouth. Can be taken with or without water.

adults and children 6 years and over	one 10 mg tablet once daily; do not take more than one 10 mg tablet in 24 hours. A 5 mg product may be appropriate for less severe symptoms.
adults 65 years and over	ask a doctor
children under 6 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). Avoid high humidity.
- **do not use if carton or blister unit is opened or broken**
- see side panel for lot number and expiration date

### **Inactive ingredients**

betadex, citric acid anhydrous, colloidal silicon dioxide, crospovidone, dl-alpha-tocopherol, hydroxypropyl cellulose, magnesium stearate, maize maltodextrin, mannitol, microcrystalline cellulose, natural flavourings, sodium bicarbonate, sodium starch glycolate and sucralose.

### **Questions or comments?**

call **1-855-274-4122** (Monday - Friday 8:30 AM to 5:00 PM EST)

NDC 0363-4025-76

DISTRIBUTED BY: WALGREEN CO.  
DEERFIELD, IL 60015

MADE IN INDIA

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL -10 mg (24 Orally Disintegrating Tablets) Blister Carton**

**ORIGINAL PRESCRIPTION STRENGTH**

**walgreens**

**Compare to the active ingredient  
in Children's Zyrtec® Allergy††**

**children's**

**Allergy Relief**

**CETIRIZINE HYDROCHLORIDE ORALLY DISINTEGRATING  
TABLETS, USP 10 mg / ANTIHISTAMINE**

**24 Hour Dissolve Tabs  
Indoor & Outdoor Allergies**

- 24-hour relief of sneezing;  
runny nose; itchy, watery eyes  
& itchy throat or nose
- Melts In your mouth

**AGES**

**6 YEARS &  
OLDER**

ACTUAL SIZE

Orange  
flavor

**24 ORALLY DISINTEGRATING TABLETS**

10 mg EACH



## CHILDRENS CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet, orally disintegrating

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0363-4025
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CETIRIZINE HYDROCHLORIDE</b> (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	10 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>BETADEX</b> (UNII: JV039JZZ3A)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	

<b>CROSPROVIDONE (35 .MU.M)</b> (UNII: 40UAA97IT9)
<b>.ALPHA.-TOCOPHEROL, DL-</b> (UNII: 7QWA1RIO01)
<b>HYDROXYPROPYL CELLULOSE (110000 WAMW)</b> (UNII: 5Y0974F5PW)
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)
<b>MANNITOL</b> (UNII: 3OWL53L36A)
<b>MICROCRYSTALLINE CELLULOSE 101</b> (UNII: 7T9FYH5QMK)
<b>MICROCRYSTALLINE CELLULOSE 102</b> (UNII: PNR0YF693Y)
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)

### Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-4025-76	4 in 1 CARTON	09/11/2020	
1		6 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	ANDA213557	09/11/2020	

**Labeler** - WALGREEN CO. (008965063)

**Registrant** - Aurohealth LLC (078728447)

### Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650918514	ANALYSIS(0363-4025) , MANUFACTURE(0363-4025)