

**CETIRIZINE HYDROCHLORIDE - cetirizine hydrochloride tablet, orally disintegrating**  
**Aurohealth LLC**

-----

***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 blister unit is torn or broken**

### **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)

Distributed by:

**AUROHEALTH LLC**

279 Princeton-Hightstown Road

East Windsor, NJ 08520

Made in India

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL -10 mg (12 Orally Disintegrating Tablets) Blister Carton**

**AUROHEALTH**

**NDC 58602-838-75**

\*Compare to the active ingredient of Zyrtec® Allergy

**Original Prescription Strength  
Cetirizine Hydrochloride  
Orally Disintegrating Tablets, USP 10 mg  
Antihistamine**

**Allergy**

***DISSOLVE TABS***

**Indoor & Outdoor Allergies**

<b>24 Hour</b> Relief of:	Sneezing	
Runny Nose	Itchy, Watery Eyes	Itchy Throat or Nose

**Dye-Free**

**Melts in your mouth  
Orange Flavor**

**Actual Size**

**12 Orally  
Disintegrating  
Tablets  
10 mg each**

--- FEB937Y ---

**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** ■ avoid alcoholic drinks ■ drowsiness may occur ■ 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 pregnant: ask a health professional before use. ■ if breast-feeding: ask a health professional before use.

**Drug Facts (continued)**

**Directions** Tablet melts in mouth. Can be taken with or without water.   
 adults and children   
 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 blister unit is torn or broken

**Inactive ingredients** betadex, citric acid anhydrous, colloidal silicon dioxide, croscollon, di-alpha-tocopherol, hydroxypropyl cellulose, magnesium stearate, maize maltoдекстрин, mannitol, microcrystalline cellulose, natural flavors, sodium bicarbonate, sodium starch glycolate and sucrose.

Distributed by:  
**AUROHEALTH LLC**  
 270 Princeton-Hightstown Road  
 East Windsor, NJ 08520

Made in India



NDC 58602-838-75  
 \*Compare to the active ingredient of Zyrtec® Allergy

**Original Prescription Strength**

## Cetirizine Hydrochloride Orally Disintegrating Tablets, USP 10 mg Antihistamine

**Allergy**

**DISSOLVE TABS**

Indoor & Outdoor Allergies      Dye-Free

24 Hour Relief of

Runny Nose	Itchy, Watery Eyes	Itchy Throat or Nose

Actual Size

**12**  
Orally Disintegrating Tablets

**10 mg each**

Melts in your mouth  
Orange Flavor

P 1058150  
 Unvarnished Zone  
 (dotted line not for printing)  
 68 x 15 mm

**Drug Facts (continued)**

**Questions or comments?** call 1-865-274-4122 (Monday - Friday 8:30 AM to 5:00 PM EST)

\*This product is not manufactured or distributed by Johnson and Johnson Consumer Inc., McNeil Consumer Healthcare Division, owner of the registered trademark Zyrtec® Allergy.

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58602-838
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>CETIRIZINE HYDROCHLORIDE</b> (UNII: 640047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	10 mg

## Inactive Ingredients

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

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:58602-838-75	2 in 1 CARTON	09/11/2020	
1	NDC:58602-838-74	6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:58602-838-76	4 in 1 CARTON	09/11/2020	
2	NDC:58602-838-74	6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:58602-838-14	11 in 1 CARTON	09/11/2020	

<b>3</b>	NDC:58602-838-74	6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
<b>4</b>	NDC:58602-838-19	20 in 1 CARTON	01/28/2025	
<b>4</b>	NDC:58602-838-74	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** - Aurohealth LLC (078728447)

## Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650918514	ANALYSIS(58602-838) , MANUFACTURE(58602-838)

Revised: 1/2025

Aurohealth LLC