

**CETIRIZINE HYDROCHLORIDE (ALLERGY) - cetirizine hydrochloride capsule**  
**Aurohealth LLC**

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**Cetirizine HCl Capsules 10 mg (Allergy)**

***Drug Facts***

***Active ingredient (in each capsule)***

Cetirizine HCl 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**

adults and children 6 years and over	one 10 mg capsule once daily; do not take more than one 10 mg capsule 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 at 20°-25°C (68°-77°F)
- avoid high humidity and excessive heat above 40°C (104°F)
- protect from light
- do not use if seal imprinted with SEALED for YOUR PROTECTION under the bottle cap is broken or missing.

**Inactive ingredients**

gelatin, glycerin, polyethylene glycol, purified water, sodium hydroxide, sorbitol sorbitan solution

**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

Code: TS/DRUGS/16/2014

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 10 mg (65's Capsule Container Label)**

**Healthy Living™**

**Allergy**

**Original Prescription Strength**

**CETIRIZINE HCl**

**Capsules 10 mg**

**Antihistamine**

**Indoor + Outdoor Allergies**

**READ AND KEEP THE OUTER PACKAGE FOR  
COMPLETE WARNINGS AND INFORMATION**

**65 LIQUID GELS\***  
**\*liquid-filled capsules**

# Top Ply

<p><b>Healthy Living™</b> Allergy <b>Original Prescription Strength</b> <b>CETIRIZINE HCl</b> capsules 10 mg Antihistamine Indoor + Outdoor Allergies 65 Liquid Gels* *liquid-filled capsules</p> <p>READ AND KEEP THE OUTER PACKAGE FOR COMPLETE WARNINGS AND INFORMATION</p>	<p>Do not use if seal imprinted with <b>SEALED for YOUR PROTECTION</b> under the bottle cap is broken or missing.</p> <p>Distributed by: AUROHEALTH LLC 279 Princeton-Hightstown Road East Windsor, NJ 08520 Made in India Code: TS/DRUGS/16/2014</p>	<table border="1"><tr><td data-bbox="998 262 1161 554"><p><b>Active ingredient (in each capsule)</b> Cetirizine HCl USP 10 mg..... <b>Uses</b> temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ runny nose ■ sneezing</p></td><td data-bbox="1161 262 1451 554"><p><b>Purpose</b> Antihistamine</p><p>LM-4693 P1428839</p><p>Lift Here</p><p>No Varnish</p></td></tr></table>	<p><b>Active ingredient (in each capsule)</b> Cetirizine HCl USP 10 mg..... <b>Uses</b> temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ runny nose ■ sneezing</p>	<p><b>Purpose</b> Antihistamine</p> <p>LM-4693 P1428839</p> <p>Lift Here</p> <p>No Varnish</p>
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## Top Ply (Page #1)

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## Back of Top Ply (Page #2)

# Bottom Ply

## Base (Page #3)

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**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL -10 mg (65's Capsule Container  
Carton Label)**

**Healthy Living™**

**Allergy**

**Original Prescription Strength**

**CETIRIZINE HCl**

**Capsules 10 mg**

**Antihistamine**

**Indoor + Outdoor Allergies**

**\*Compare  
to the Active  
Ingredient in  
Zyrtec®**

**CZ10**

**(Actual Size)**

**24 Hour Relief of: • Sneezing • Runny Nose  
• Itchy, Watery Eyes • Itchy Throat or Nose  
capsules**

**65 Liquid Gels\*  
\*liquid-filled**



## CETIRIZINE HYDROCHLORIDE (ALLERGY)

cetirizine hydrochloride capsule

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58602-716
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>GELATIN, UNSPECIFIED</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>SORBITOL</b> (UNII: 506T60A25R)	

### Product Characteristics

<b>Color</b>	YELLOW (Clear colourless to pale yellow viscous liquid)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	13mm
<b>Flavor</b>		<b>Imprint Code</b>	CZ10
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-716-16	1 in 1 CARTON	08/16/2022	
1		65 in 1 BOTTLE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209107	08/16/2022	

**Labeler** - Aurohealth LLC (078728447)

### Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	ANALYSIS(58602-716) , MANUFACTURE(58602-716)

### Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(58602-716) , MANUFACTURE(58602-716)

Revised: 8/2022

Aurohealth LLC