

**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
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- in rare cases, you may experience itching after stopping cetirizine. Consult your healthcare provider if this happens.

**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

**Inactive ingredients**

black iron oxide, gelatin, glycerin, hypromellose, polyethylene glycol, propylene 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)

\*This product is not manufactured or distributed by the owners of Zyrtec®.

Distributed by:

**AUROHEALTH LLC**

279 Princeton-Hightstown Road  
East Windsor, NJ 08520

Made in India

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 10 mg (12's Capsule Container Label)**

**NDC 58602-806-04**

**Cetirizine HCl Capsules**

**10 mg**

**Antihistamine**

**Indoor & Outdoor**

**Allergies**

**CZ10**

**(Actual size)**

**KEEP CARTON FOR COMPLETE WARNINGS  
AND PRODUCT INFORMATION**

**AUROHEALTH**

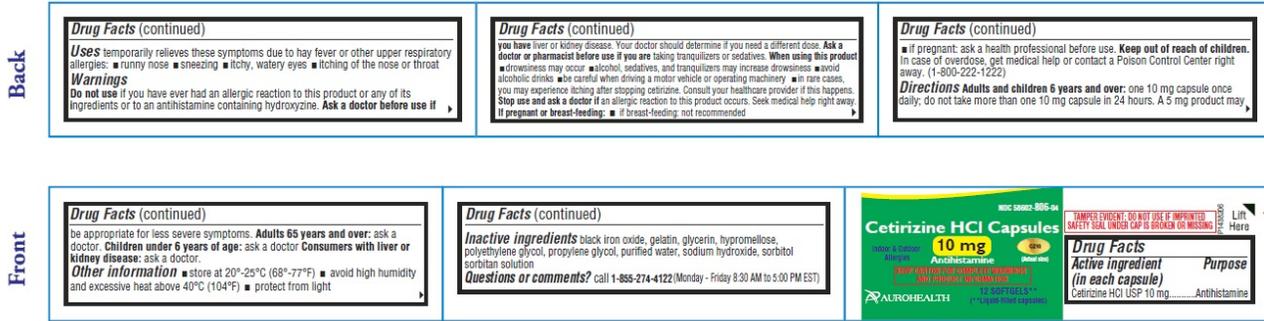
**12 SOFTGELS\*\***

**(\*\* Liquid-filled capsules)**

# Base Label



## Booklet



## PACKAGE LABEL-PRINCIPAL DISPLAY PANEL -10 mg (12's Capsule Container Carton Label)

**NDC 58602-806-04**

**\*Compare to the active ingredient in Zyrtec®**

**Cetirizine HCl Capsules**

**10 mg**

**Antihistamine**

**Indoor & Outdoor  
Allergies**

**CZ10  
(Actual size)**

**24 HOUR**

**Relief of:**

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose

**AUROHEALTH**

**12 SOFTGELS\*\***

**(\*\* Liquid-filled capsules)**



## CETIRIZINE HYDROCHLORIDE (ALLERGY)

cetirizine hydrochloride capsule

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58602-806
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>GELATIN, UNSPECIFIED</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C00X)	
<b>HYPROMELLOSE 2910 (6 MPA.S)</b> (UNII: 0WZ8WG20P6)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<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:58602-806-04	1 in 1 CARTON	07/20/2018	
1		12 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-806-53	1 in 1 CARTON	07/20/2018	
2		25 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58602-806-12	1 in 1 CARTON	07/20/2018	
3		40 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:58602-806-16	65 in 1 CARTON	07/20/2018	
4		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	07/20/2018	

**Labeler** - Aurohealth LLC (078728447)

### Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	ANALYSIS(58602-806) , MANUFACTURE(58602-806)

## Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(58602-806) , MANUFACTURE(58602-806)

Revised: 2/2026

Aurohealth LLC