

**CETIRIZINE HYDROCHLORIDE (ALLERGY) - cetirizine hydrochloride capsule  
WALGREEN CO.**

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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***

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)

DISTRIBUTED BY: **WALGREEN CO.**  
**200 WILMOT RD., DEERFIELD, IL 60015**

**100% SATISFACTION GUARANTEED**  
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**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 10 mg (25's Capsule Container Label)**

**ORIGINAL**  
**PRESCRIPTION STRENGTH            NDC 0363-0068-53**  
**walgreens**  
**Allergy Relief**

**24 HOUR ALLERGY**  
**CETIRIZINE HCl CAPSULES 10 mg / ANTIHISTAMINE**

- **Indoor & outdoor allergies**

**25 LIQUID GELS\*\***  
**(\*\*LIQUID-FILLED CAPSULES)**

# TOP VERSION 1

<b>ORIGINAL PRESCRIPTION STRENGTH</b> NDC 0363-0068-53		<b>DO NOT USE IF SEAL IMPRINTED WITH SEALED FOR YOUR PROTECTION UNDER THE BOTTLE CAP IS BROKEN OR MISSING</b>	
<b>Walgreens</b>		<b>READ AND KEEP THE OUTER PACKAGE FOR COMPLETE WARNINGS AND INFORMATION</b>	
<b>Allergy Relief</b> • Indoor & outdoor allergies <b>24 HOUR ALLERGY</b> CETIRIZINE HCl CAPSULES 10 mg / ANTIHISTAMINE <b>25 LIQUID GELS**</b> (**liquid-filled capsules)		DISTRIBUTED BY: WALGREEN CO. 200 WILMOT RD., DEERFIELD, IL 60015 <b>100% SATISFACTION GUARANTEED</b> walgreens.com ©2021 Walgreen Co. ITEM 896824 W000000-0000-0 W3ORG0821-F MADE IN INDIA CODE: TS/DRUGS/16/2014	
		<b>Drug Facts</b> <b>Active ingredient</b> (in each capsule) Cetirizine HCl USP 10 mg.....Antihistamine	<b>Purpose</b> Lift Here P 1435902 LM-4620
		<b>Uses</b> temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ runny nose ■ sneezing	

\*Over Printing Zone

Coding Area  
(27 x 11 mm)

Dotted lines not to be printed

Lot: XXXXXXXX  
 EXP: MM/YYYY  
 Prefix & Variables of Lot, EXP  
 shall be printed online during packing.

# INSIDE

<b>Drug Facts (continued)</b> ■ itchy, watery eyes ■ itching of the nose or throat <b>Warnings</b> <b>Do not use</b> if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine. <b>Ask a doctor before use if you have</b> liver or kidney disease. Your doctor should determine if you need a different dose. <b>Ask a doctor or pharmacist before use if you are</b> taking tranquilizers or sedatives. <b>When using this product</b> ■ drowsiness may occur ■ avoid alcoholic drinks ■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ be careful when driving a motor vehicle or operating machinery <b>Stop use and ask a doctor if an allergic reaction to this product occurs.</b> Seek medical help right away. <b>If pregnant or breast-feeding:</b> ■ if breast-feeding: not recommended ■ if pregnant: ask a health professional before use. <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)	P1435902 LM-4620
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# BASE

<b>Drug Facts (continued)</b> <b>Directions</b> <b>Adults and children 6 years and over:</b> 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. <b>Adults 65 years and over:</b> ask a doctor. <b>Children under 6 years of age:</b> ask a doctor <b>Consumers with liver or kidney disease:</b> ask a doctor. <b>Other information</b> ■ 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. <b>Inactive ingredients</b> black iron oxide, gelatin, glycerin, hypromellose, polyethylene glycol, propylene glycol, purified water, sodium hydroxide, sorbitol sorbitan solution <b>Questions or comments?</b> call 1-855-274-4122 (Monday - Friday 8:30 AM to 5:00 PM EST)	P1435902 LM-4620
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**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL -10 mg (25's Capsule Container Carton Label)**

**ORIGINAL PRESCRIPTION STRENGTH**

NDC 0363-0068-53

**walgreens**

Compare to the active ingredient in  
Zyrtec®††

Allergy Relief

24 HOUR ALLERGY

CETIRIZINE HCl CAPSULES 10 mg / ANTIHISTAMINE

24 Hour

Liquid Gels

Indoor & Outdoor Allergies

- Relief of sneezing; runny nose;  
itchy, watery eyes & itchy throat or nose

CZ10

ACTUAL SIZE

25

LIQUID

GELS\*\*

(\*\*liquid-filled capsules)





## CETIRIZINE HYDROCHLORIDE (ALLERGY)

cetirizine hydrochloride capsule

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0068
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>FERROSOFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>GELATIN, UNSPECIFIED</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<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:0363-0068-53	1 in 1 CARTON	06/08/2020	
1		25 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0363-0068-12	1 in 1 CARTON	06/08/2020	
2		40 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	06/08/2020	

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

**Registrant** - Aurohealth LLC (078728447)

## Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	ANALYSIS(0363-0068) , MANUFACTURE(0363-0068)

## Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(0363-0068) , MANUFACTURE(0363-0068)

Revised: 4/2025

WALGREEN CO.