

**CETIRIZINE HYDROCHLORIDE (ALLERGY) - cetirizine hydrochloride tablet**  
**Better Living Brands, LLC**

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**Cetirizine Hydrochloride Tablets USP 10 mg**

***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**

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)
- **TAMPER EVIDENT: DO NOT USE IF SEAL OVER BOTTLE OPENING IS BROKEN OR MISSING.**

## **Inactive Ingredients**

colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide.

## **Questions?**

call **1-855-274-4122**

## **DISTRIBUTED BY:**

BETTER LIVING BRANDS LLC  
P.O.BOX 99, PLEASANTON  
CA 94566-0009  
‡1-888-723-3929

Made in India

Code: TS/DRUGS/19/1993

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 10 mg (120's Tablet Bottle)**  
**NDC 21130-098-23**

**Signature**  
**care®**  
Quality Guaranteed

**Original Prescription Strength**

**Allergy Relief**  
**Cetirizine Hydrochloride**  
**Tablets USP 10 mg**

**Antihistamine**

**120 Tablets**  
**10 mg each**

**Signature care®**  
Quality Guaranteed

NDC 21130-098-23

Do not use if seal over bottle opening is broken or missing.

**Original Prescription Strength**  
**Allergy Relief**  
**Cetirizine Hydrochloride**  
**Tablets USP 10 mg**  
**Antihistamine**

120 Tablets  
10 mg each

**Drug Facts**

**Active Ingredient (in each tablet)** Purpose  
Cetirizine hydrochloride USP 10 mg.....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 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) **Inactive ingredients** colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide

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P.O. BOX 99, PLEASANTON, CA 94566-0099  
Made in India  
1-888-723-3929

Code: TS/DRUGS/19/1993

Lot: P 1432721  
Exp.: L M - 5205

NVZ

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 10 mg (120's Container Carton Label)**

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

**NDC 21130-098-23**

**Signature**  
**care®**  
Quality Guaranteed

**Original Prescription Strength**

# Allergy Relief Cetirizine Hydrochloride Tablets USP 10 mg

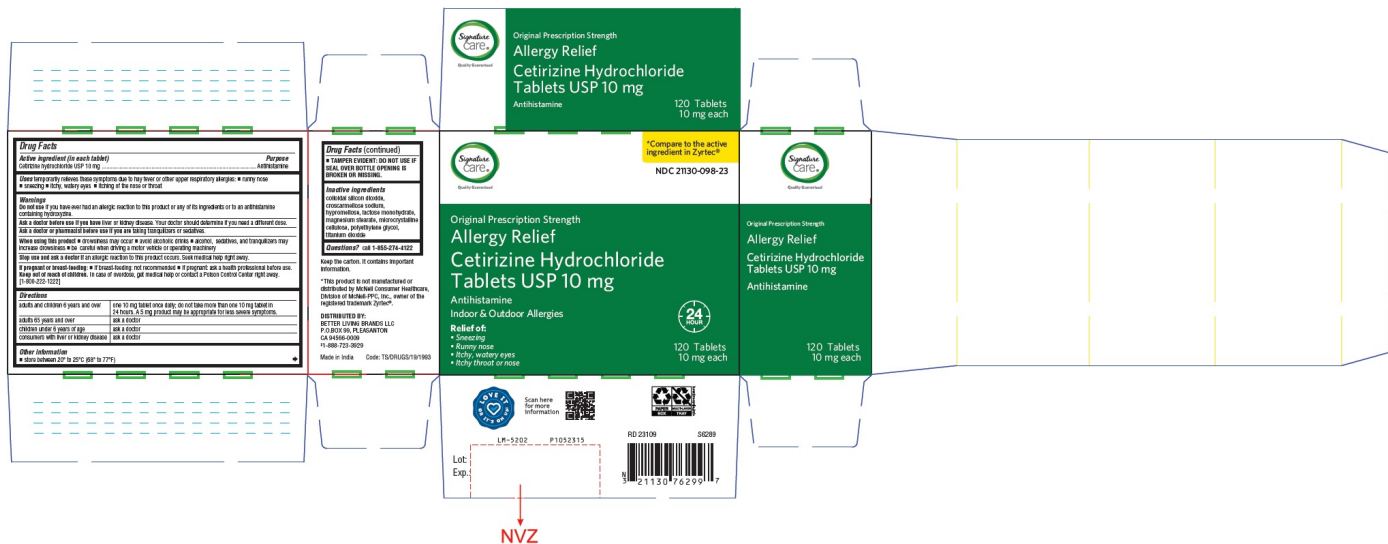
## Antihistamine Indoor & Outdoor Allergies

24  
HOUR

Relief of:

- Sneezing
- Runny nose
- Itchy, watery eyes
- Itchy throat or nose

120 Tablets  
10 mg each



## CETIRIZINE HYDROCHLORIDE (ALLERGY)

cetirizine hydrochloride tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:21130-098
<b>Route of Administration</b>	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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

Color	WHITE (White to Off-white)	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	X;36
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-098-23	1 in 1 CARTON	05/19/2023	
1		120 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:21130-098-39	365 in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2023	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090760	05/19/2023	

**Labeler** - Better Living Brands, LLC (009137209)

**Registrant** - Aurohealth LLC (078728447)

## Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		918917642	ANALYSIS(21130-098) , MANUFACTURE(21130-098)