

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

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:

BETTER LIVING BRANDS LLC

P.O.BOX 99, PLEASANTON
CA 94566-0009
†1-888-723-3929

Made in India
Code: TS/DRUGS/22/2009

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 10 mg (25's Capsule Container Label)

NDC 21130-099-97

Signature

care®
Quality
Guaranteed

**Original Prescription Strength
Allergy**

**CETIRIZINE HCl capsules 10 mg
Antihistamine**

Indoor + Outdoor Allergies

25 Liquid Gels**

****liquid-filled capsules**

Top Ply

Signature Care
NDC 21130-099-97

Original Prescription Strength
Allergy
CETIRIZINE HCl capsules 10 mg
Antihistamine

Indoor + Outdoor Allergies 25 Liquid Gels**
**liquid-filled capsules

Do not use if seal imprinted with SEALED for YOUR PROTECTION under the bottle cap is broken or missing.
READ AND KEEP THE OUTER PACKAGE FOR COMPLETE WARNINGS AND INFORMATION

DISTRIBUTED BY:
BETTER LIVING BRANDS LLC
P.O. BOX 99, PLEASANTON, GA 30456-0099
1-888-723-3929
Made in India
Code: TS/DRUGS/16/2014
RD 23095 S6289

Drug Facts
Active ingredient (in each capsule)
Cetirizine HCl USP 10 mg.....Antihistamine

Purpose
Lift Here

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
■ runny nose
■ sneezing

P1432658 LM-5204

No Varnish

Top Ply
(Page #1)

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

Drug Facts (continued)
■ 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)

P1432658 LM-5204

HINGE

Back of Top Ply

(Page #2)

Bottom Ply

Base
(Page #3)

Drug Facts (continued)

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)

P1432658 LM-5204

HINGE

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL -10 mg (25's Capsule Container Carton Label)

Signature
care®
Quality

Guaranteed

**COMPARE TO Zyrtec®
Active Ingredient***

NDC 21130-099-97

**Original Prescription Strength
Allergy**

**CETIRIZINE HCl capsules 10 mg
Antihistamine**

Indoor + Outdoor Allergies

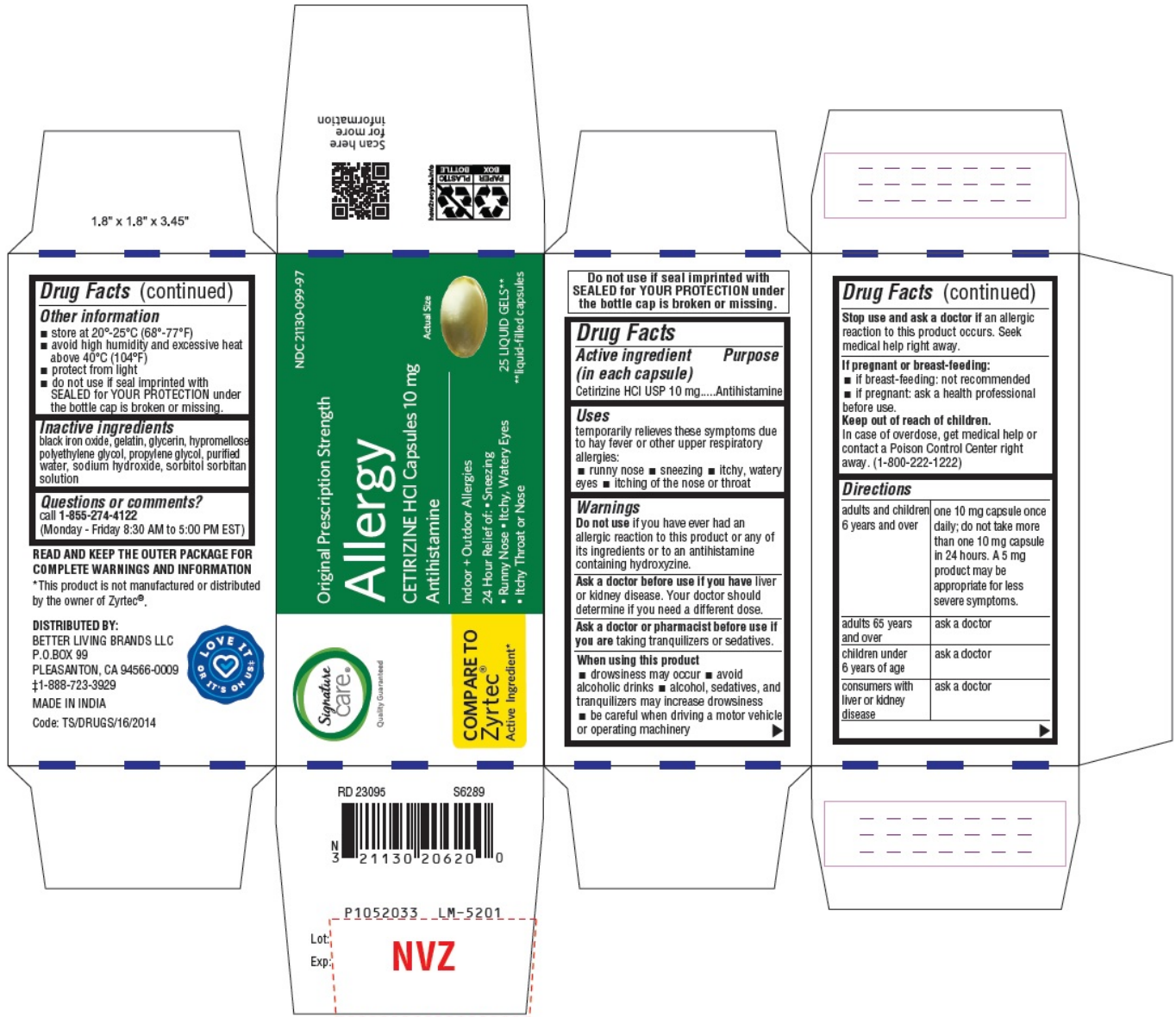
24 Hour Relief of:

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

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:21130-099
Route of Administration	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
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-099-97	1 in 1 CARTON	11/15/2023	
1		25 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	11/15/2023	

Labeler - Better Living Brands, LLC (009137209)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(21130-099) , MANUFACTURE(21130-099)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	ANALYSIS(21130-099) , MANUFACTURE(21130-099)