CETIRIZINE HYDROCHLORIDE (ALLERGY) - cetirizine hydrochloride capsule Aurohealth 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:
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 (40's Capsule Container Label)

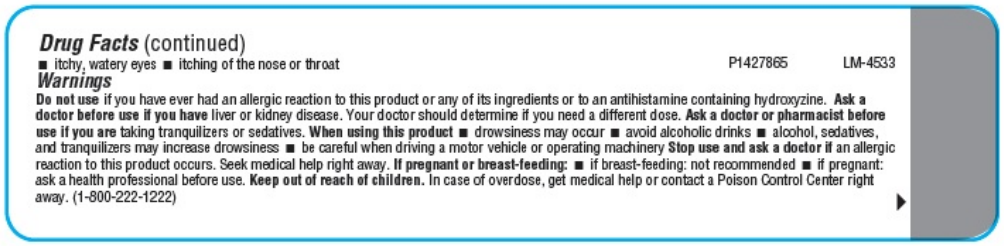
PrimaryHealth NDC 58602-863-12
ALLERGY
Original
Prescription Strength

Cetirizine HCl Capsules
10 mg
Antihistamine
INDOOR + OUTDOOR ALLERGIES

40 LIQUID GELS*
*** LIQUID-FILLED CAPSULES***

Top Ply

Top Ply
(Page #1)



Back of Top Ply

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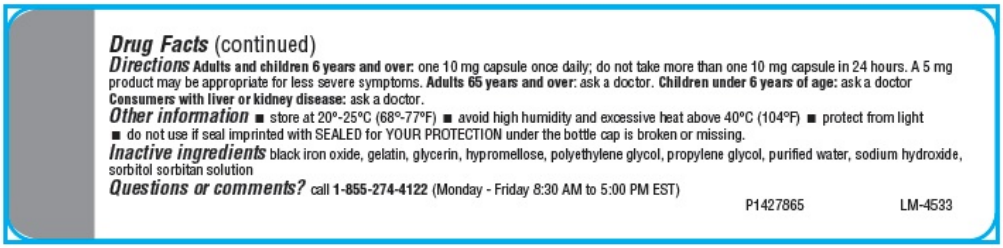
Bottom Ply

Base
(Page #3)



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL -10 mg (40's Capsule Container Carton Label)

NDC 58602-863-12
PrimaryHealth
COMPARE TO Zyrtec®
active ingredient*
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**

CZ10
(Actual size)

40 *LIQUID GELS**
*** *LIQUID-FILLED CAPSULES***

CETIRIZINE HYDROCHLORIDE (ALLERGY)

cetirizine hydrochloride capsule

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58602-863
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**

FERROSOFERRIC 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:58602-863-12	1 in 1 CARTON	03/12/2021	
1		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	03/12/2021	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(58602-863) , MANUFACTURE(58602-863)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	ANALYSIS(58602-863) , MANUFACTURE(58602-863)

Revised: 3/2021 Aurohealth LLC