

CETIRIZINE HYDROCHLORIDE (ALLERGY) - cetirizine hydrochloride capsule
RITE AID CORPORATION

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

gelatin, glycerin, polyethylene 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: RITE AID,
30 HUNTER LANE, CAMP HILL,
PA 17011 **www.riteaid.com**

MADE IN INDIA

Code: TS/DRUGS/16/2014

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

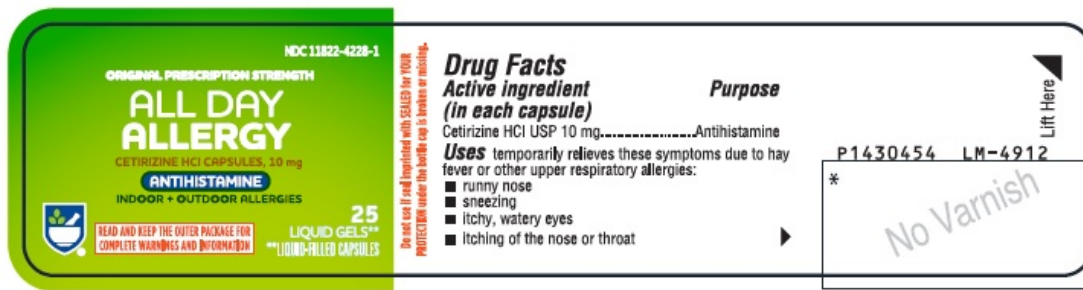
**NDC 11822-4228-1
ORIGINAL PRESCRIPTION STRENGTH
ALL DAY
ALLERGY**

**CETIRIZINE HCl CAPSULES, 10 mg
ANTIHISTAMINE
INDOOR + OUTDOOR ALLERGIES**

**READ AND KEEP THE OUTER PACKAGE FOR
25
COMPLETE WARNINGS AND INFORMATION
GELS****

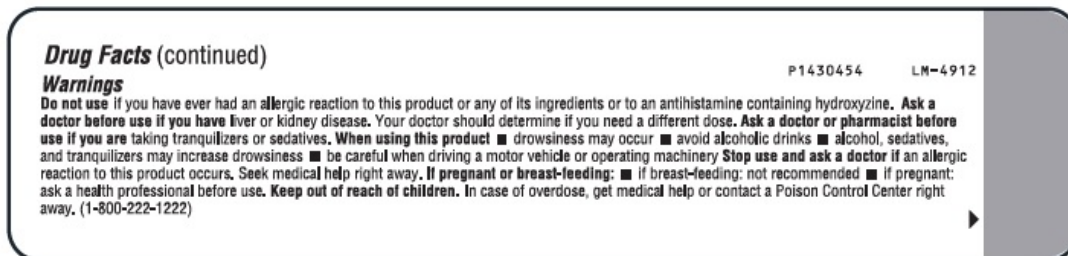
LIQUID

****LIQUID-FILLED CAPSULES**



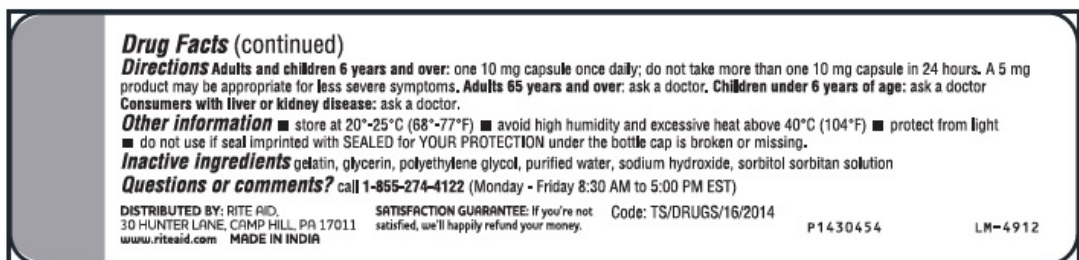
**Top Ply
(Page #1)**

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



**Back of Top Ply
(Page #2)**

**Base
(Page #3)**



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

NDC 11822-4228-1

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

ORIGINAL

PRESCRIPTION STRENGTH

**ALL DAY
ALLERGY**

**CETIRIZINE HCl
CAPSULES, 10 mg**

**ANTI-HISTAMINE
INDOOR +OUTDOOR
ALLERGIES**

24-HOUR RELIEF OF

Sneezing

Runny nose

Itchy, watery eyes

Itchy throat or nose

ACTUAL SIZE

CZ10

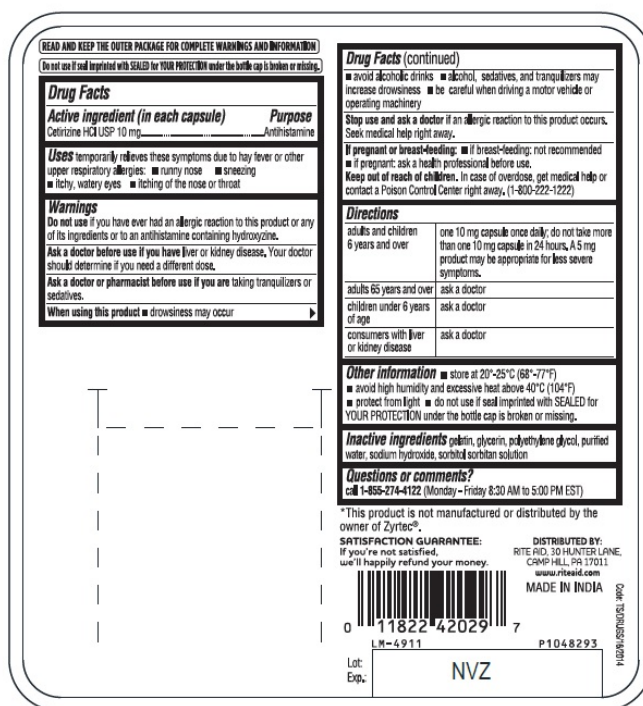
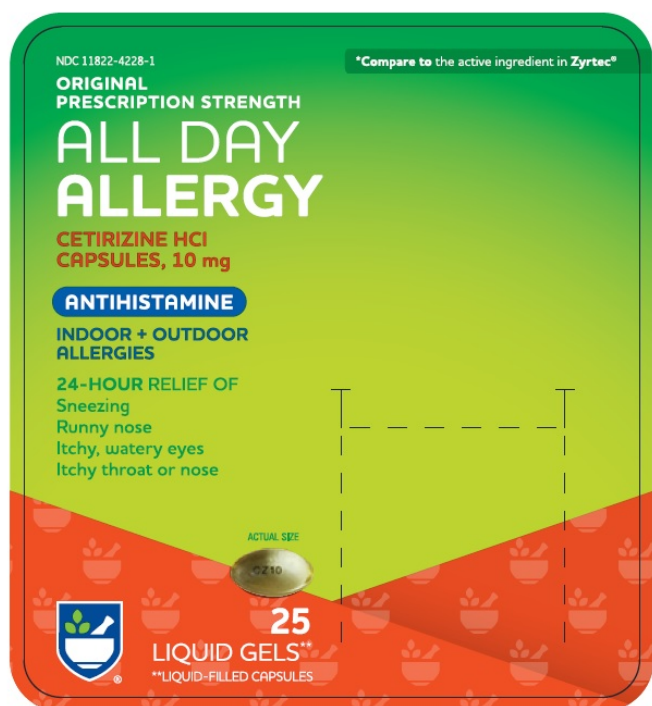
25

LIQUID GELS**

**LIQUID-FILLED CAPSULES

Front

Back



CETIRIZINE HYDROCHLORIDE (ALLERGY)

cetirizine hydrochloride capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-4228
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
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	YELLOW (Clear colourless to pale yellow viscous liquid)	Score	no score
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Shape	OVAL	Size	13mm	
Flavor		Imprint Code	CZ10	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-4228-1	1 in 1 CARTON	06/24/2022	
1		25 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:11822-4228-2	1 in 1 CARTON	06/24/2022	
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	06/24/2022		

Labeler - RITE AID CORPORATION (014578892)

Registrant - Aurohealth LLC (078728447)

Establishment			
Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	ANALYSIS(11822-4228) , MANUFACTURE(11822-4228)

Establishment			
Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(11822-4228) , MANUFACTURE(11822-4228)