CETIRIZINE HYDROCHLORIDE - cetirizine hydrochloride tablet, orally disintegrating
TOPCO ASSOCIATES LLC

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

Tablet melts in mouth. Can be taken with or without water.

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). Avoid high humidity.
- **do not use if carton or blister unit is opened or broken**
- see side panel for lot number and expiration date

Inactive ingredients

betadex, citric acid anhydrous, colloidal silicon dioxide, crospovidone, dl-alpha-tocopherol, hydroxypropyl cellulose, magnesium stearate, maize maltodextrin, mannitol, microcrystalline cellulose, natural flavourings, sodium bicarbonate, sodium starch glycolate and sucralose.

Questions or comments?

call **1-855-274-4122** (Monday - Friday 8:30 AM to 5:00 PM EST)

DISTRIBUTED BY:
TOPCO ASSOCIATES LLC
ELK GROVE VILLAGE, IL 60007

QUESTIONS? 1-888-423-0139

MADE IN INDIA

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL -10 mg (24 Orally Disintegrating Tablets) Blister Carton

+TopCare®
health

NDC 76162-009-76

COMPARED TO ZYRTEC® ALLERGY
ACTIVE INGREDIENT*

ORIGINAL PRESCRIPTION STRENGTH
ALLERGY

Cetirizine Hydrochloride
ORALLY DISINTEGRATING TABLETS, USP 10 mg
ANTIHISTAMINE

INDOOR & OUTDOOR ALLERGIES

24 HOUR
RELIEF

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

24 ORALLY DISINTEGRATING TABLETS 10 MG EACH
DISSOLVE TABLETS • MELTS IN YOUR MOUTH • ORANGE FLAVOR

actual size 10

CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet, orally disintegrating

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76162-009
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
BETADEX (UNII: JV039JZZ3A)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPOVIDONE (35 .MU.M) (UNII: 40UAA97IT9)	
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01)	
HYDROXYPROPYL CELLULOSE (110000 WAMW) (UNII: 5Y0974F5PW)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MANNITOL (UNII: 3OWL53L36A)	
MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	WHITE	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor	ORANGE	**Imprint Code**	CE;10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76162-009-76	4 in 1 CARTON	06/06/2024	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA213557	06/06/2024	

Labeler - TOPCO ASSOCIATES LLC (006935977)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650918514	ANALYSIS(76162-009) , MANUFACTURE(76162-009)

Revised: 6/2024 TOPCO ASSOCIATES LLC