CETIRIZINE HYDROCHLORIDE - cetirizine hydrochloride tablet, orally disintegrating
Aurohealth 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: **AUROHEALTH LLC**
2572 Brunswick Pike
Lawrenceville, NJ 08648

Made in India

Code: AP/DRUGS/04/2016

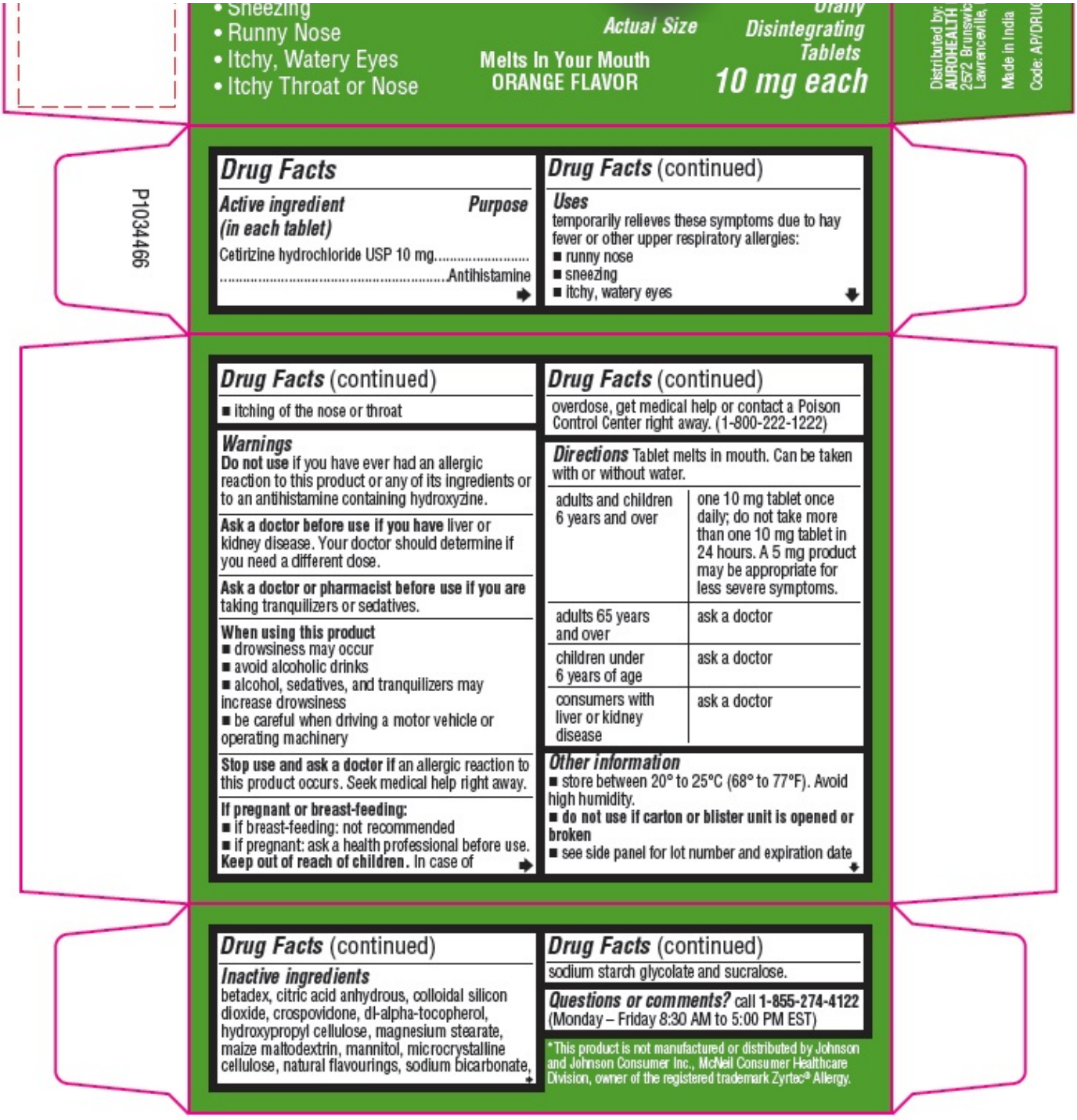
PACKAGE LABEL-PRINCIPAL DISPLAY PANEL -10 mg (12 Orally Disintegrating Tablets) Blister Carton

AUROHEALTH
NDC 58602-838-75
*Compare to the active
ingredient of Zyrtec® Allergy
Original Prescription Strength
Cetirizine Hydrochloride
Orally Disintegrating Tablets, USP 10 mg
Antihistamine
Allergy
Dissolve Tabs
Indoor + Outdoor Allergies
24 Hour Relief of:

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

Melts In Your Mouth
ORANGE FLAVOR
Actual Size

12 *Orally*
Disintegrating
Tablets
10 mg each



CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet, orally disintegrating

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58602-838
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:58602-838-75	2 in 1 CARTON	09/11/2020	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:58602-838-76	4 in 1 CARTON	09/11/2020	
2		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:58602-838-14	11 in 1 CARTON	09/11/2020	
3		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	09/11/2020	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650918514	ANALYSIS(58602-838) , MANUFACTURE(58602-838)

Revised: 4/2021 Aurohealth LLC