CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet
Granules USA, Inc.

CETIRIZINE HYDROCHLORIDE TABLETS, USP 10 mg
ANTIHISTAMINE
24 HOUR
INDOOR & OUTDOOR ALLERGIES

Active ingredient

(in each tablet)
Cetirizine HCl 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

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 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)
■ contains no ingredient made from a gluten-containing grain (Wheat, barley or rye)

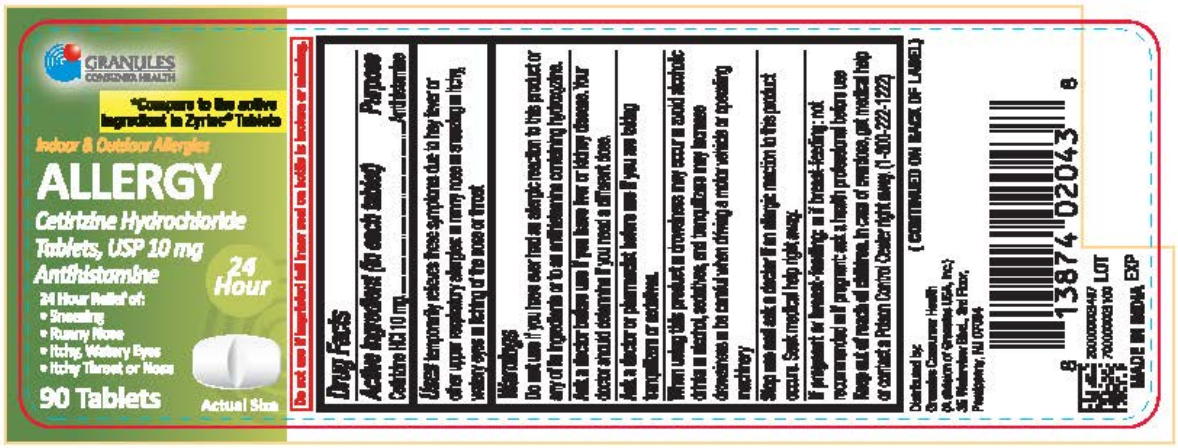
Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide.

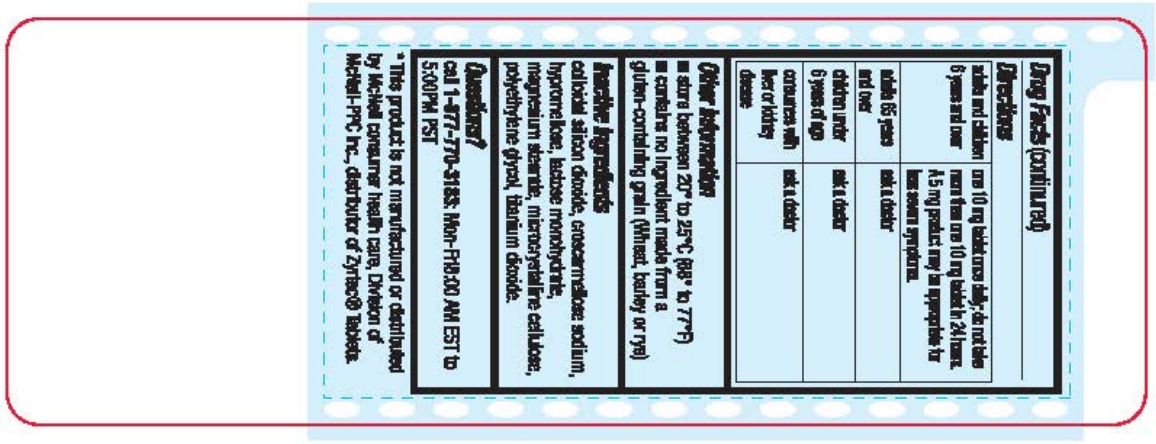
Questions?

call **1-877-770-3183**: Mon-Fri 8:00 AM EST to 5:00 PM PST

PDP



Inside (adhesive side)



CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69848-006
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**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	

HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white (White to off-white)	**Score**	2 pieces
Shape	RECTANGLE (round-off rectangular shaped tablets)	**Size**	9mm
Flavor		**Imprint Code**	G;4
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69848-006-09	90 in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209274	06/30/2021	

Labeler - Granules USA, Inc. (137098864)

Revised: 12/2023 Granules USA, Inc.