

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

GRANULES
CONSUMER HEALTH

"Compare to the active ingredient in Zyrtec® Tablets"

Indoor & Outdoor Allergies

ALLERGY

Cetirizine Hydrochloride Tablets, USP 10 mg

Antihistamine

24 Hour

24 Hour Relief of:

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

90 Tablets

Actual Size

Do not use if Impaired but never use inside a vehicle or while driving.

Drug Facts

Active ingredient (in each tablet) Antihistamine
Cetirizine HCl 10 mg

Uses Temporarily relieves these symptoms in hay fever or other respiratory allergies in many cases in 1 hour in many cases in 1 hour of the onset of these symptoms.

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 in crowded areas may occur in some individuals drowsiness, dizziness, and weakness may increase. Do not use if you are 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, or if breast-feeding, not recommended. If pregnant, ask a health professional before use. Keep out of reach of children. In case of emergency, get medical help or contact a Poison Control Center right away (1-800-222-1222).

(CONTINUED ON BACK OF LABEL)

Distributed by:
Granules Consumer Health
A Division of Wyeth USA, Inc.
200 Madison Ave., 20th Floor
Philadelphia, PA 19106

8 13874 02043 **8**

2000002847 LOT
2000002100
EXP
MADE IN INDIA

Inside (adhesive side)

Drug Facts (continued)

Directions

adults and children 6 years and over: one (1) mg tablet once daily; do not take more than one (1) mg tablet in 24 hours. It is 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

contains with less or drowsiness: ask a doctor

Other Information

Store between 20° to 25°C (68° to 77°F) in container no ingredient made from a gluten-containing grain (wheat, barley or rye).

Inactive Ingredients

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

Questions?

This product is not manufactured or distributed by McNeil-PPC, Inc., distributor of Zyrtec® Tablets. For more information, call 1-877-770-5183, Mon-Fri 9:00 AM EST to 5:00 PM PST.

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)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	

HYPROMELLOSES (UNII: 3NXW29V3WO)					
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)					
MAGNESIUM STEARATE (UNII: 70097M6I3O)					
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)					
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)					
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)