CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet, coated
Granules Pharmaceuticals Inc.

Cetrizine Hydrochloride Tablets

Cetirizine Hydrochloride Tablets

Drug Facts

Active Ingredient

Cetirizine HCl 10 mg

PURPOSE

Antihistamine

USE(S)

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

liver or kidney disease. Your doctor should determine if you need a different dose.

ASK A DOCTOR OR PHARMACIST BEFORE USE IF

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 DOCTOR IF

an allergic reaction to this product occurs. Seek medical help right away.

PREGNANCY/BREASTFEEDING

- 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

STORAGE

- store between 20° to 25°C (68° to 77°F)

Other information

■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.

PRINCIPAL DISPLAY PANEL

Front Top

NDC 70010-163-05

*Compare to the active ingredient in Zyrtec® Tablets

Indoor & Outdoor Allergies

Cetirizine Hydrochloride Tablets, USP

Allergy

10 mg

24 Hour

Antihistamine

24 Hour Relief of:

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

Actual Size

500 Tablets

Do not use if imprinted foil inner seal on bottle is broken or missing.

Drug Facts

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

(CONTINUED ON BACK OF LABEL)

Distributed by:
Granules Pharmaceuticals Inc.
Chantilly, VA 20151

MADE IN INDIA

Rev.12/21
LL0131-00
AP/DRUGS/37/2003
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PEEL HERE

Coating Free

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Drug Facts (continued)

Directions

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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)

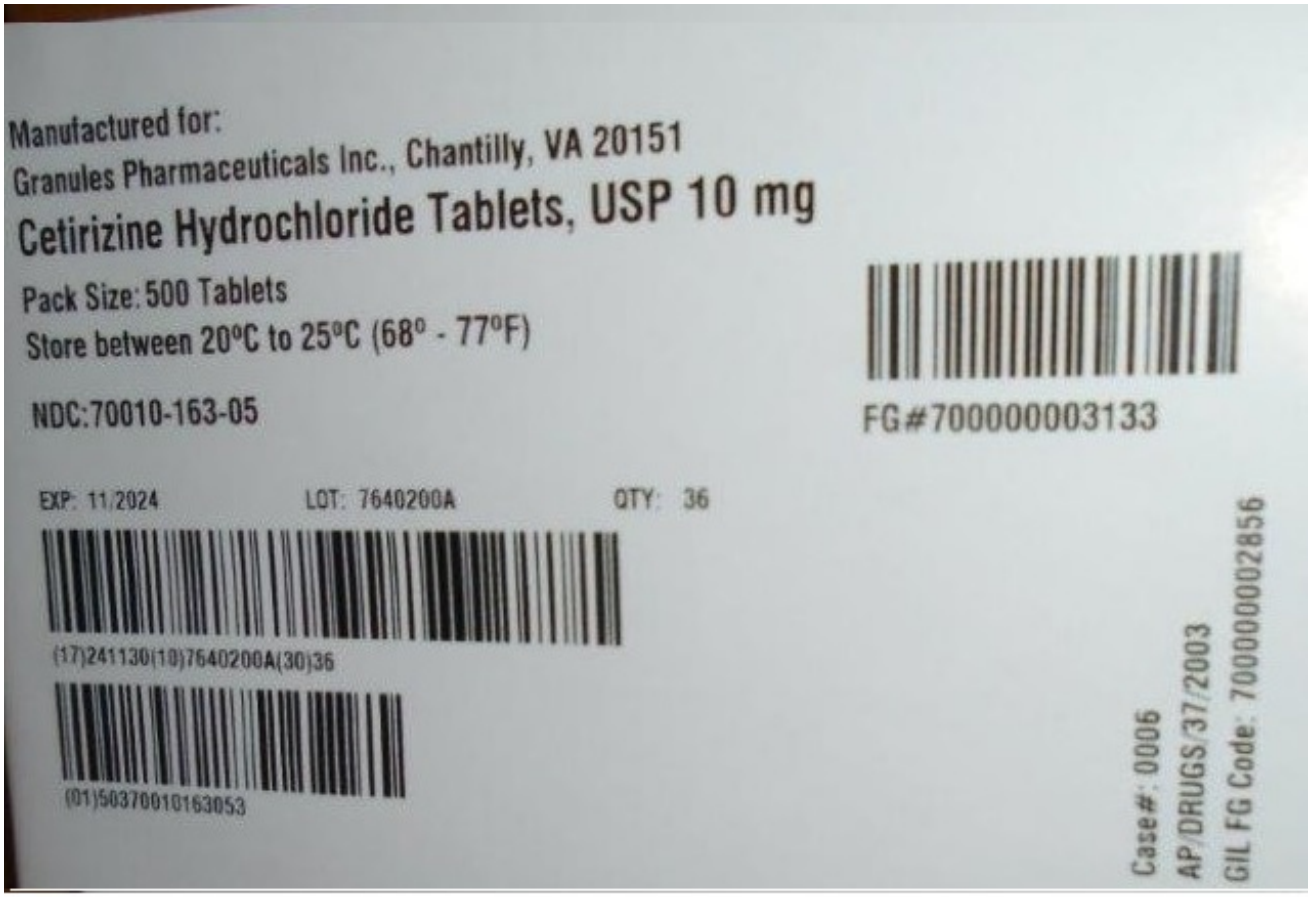
Inactive ingredients

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

* This product is not manufactured or distributed by McNeil consumer health care, Division of McNeil-PPC Inc., distributor of Zyrtec® Tablets.



CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70010-163
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**
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL (UNII: 3WQ0SDW1A)	

Product Characteristics			
Color	white (white to off white)	**Score**	2 pieces
Shape	RECTANGLE (rounded off rectangualr)	**Size**	9mm
Flavor		**Imprint Code**	G;4
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70010-163-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/13/2022	
2	NDC:70010-163-09	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/26/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209274	01/13/2022	

Labeler - Granules Pharmaceuticals Inc. (079825711)

Establishment

Name	Address	ID/FEI	Business Operations
Granules India Ltd		918609236	manufacture(70010-163)

Revised: 1/2023 Granules Pharmaceuticals Inc.