

**CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet, coated
Granules India Ltd**

Cetirizine 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

NDC 13281-754-73

Cetirizine Hydrochloride Tablets USP, 10 mg

Antihistamine

Indoor & Outdoor Allergies

ALLERGY

130 Tablets (13 x 10 Unit-dose)

24 Hour Relief of • Sneezing
• Runny Nose • Itchy, Watery Eyes
• Itchy Throat or Nose

Compare to the active ingredient in
Zyrtec® Tablets*



Lot
or
Un Varnish area



Drug Facts

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

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 tricyclics or sedatives.

When using this product:
• Alcohol may cause drowsiness or dizziness.
• Alcohol, sedatives, and tranquilizers may increase drowsiness. • Be careful when driving a motor vehicle or operating machinery.

Drug Facts (continued)

Keep out of reach of children. If an allergic reaction to this product occurs, seek medical help right away.

If pregnant or breast-feeding:
• If pregnant or breast-feeding, do not take this product.
• If pregnant, ask a health professional before use. Keep out of reach of children. In case of over dose, get medical help or contact a Poison Control Center right away. (1-800-368-3333)

Directions
Take 10 mg tablet once daily, or as often as needed, but not more than once 10 mg tablet in 24 hours. A 10 mg product may be appropriate for less severe symptoms.

Adults 18 years and over: Take 10 mg tablet once daily.

Children 6 years and over: Take 5 mg tablet once daily.

Children 2 to 5 years: Ask a doctor.

Children 6 months to 2 years: Ask a doctor.

Children under 6 months: Ask a doctor.

NDC 13281-754-73

Cetirizine Hydrochloride Tablets USP, 10 mg

Antihistamine

Indoor & Outdoor Allergies

ALLERGY

130 Tablets (13 x 10 Unit-dose)

24 Hour Relief of • Sneezing
• Runny Nose • Itchy, Watery Eyes
• Itchy Throat or Nose

Compare to the active ingredient in
Zyrtec® Tablets*



Manufactured by:
Gencor India Limited
Hyderabad - 500 081, India
MADE IN INDIA

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M.L. No.: 219049/2005/18

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NDC 6200-764-73
Cetirizine Hydrochloride
Tablet USP, (10 mg)
ANTHISTAMINE
PEAL PUS H
Mfg. By: Granules India Limited
Made in India
LOT:
EXP:-

NDC 6200-764-43
Cetirizine Hydrochloride
Tablet USP, (10 mg)
ANTHISTAMINE
PEAL PUS H
Mfg. By: Granules India Limited
Made in India
LOT:
EXP:-

NDC 6200-764-73
Cetirizine Hydrochloride
Tablet USP, (10 mg)
ANTHISTAMINE
PEAL PUS H
Mfg. By: Granules India Limited
Made in India
LOT:
EXP:-

NDC 6200-764-43
Cetirizine Hydrochloride
Tablet USP, (10 mg)
ANTHISTAMINE
PEAL PUS H
Mfg. By: Granules India Limited
Made in India
LOT:
EXP:-

NDC 6200-764-73
Cetirizine Hydrochloride
Tablet USP, (10 mg)
ANTHISTAMINE
PEAL PUS H
Mfg. By: Granules India Limited
Made in India
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EXP:-

NDC 6200-764-43
Cetirizine Hydrochloride
Tablet USP, (10 mg)
ANTHISTAMINE
PEAL PUS H
Mfg. By: Granules India Limited
Made in India
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NDC 6200-764-73
Cetirizine Hydrochloride
Tablet USP, (10 mg)
ANTHISTAMINE
PEAL PUS H
Mfg. By: Granules India Limited
Made in India
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NDC 6200-764-43
Cetirizine Hydrochloride
Tablet USP, (10 mg)
ANTHISTAMINE
PEAL PUS H
Mfg. By: Granules India Limited
Made in India
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NDC 6200-764-73
Cetirizine Hydrochloride
Tablet USP, (10 mg)
ANTHISTAMINE
PEAL PUS H
Mfg. By: Granules India Limited
Made in India
LOT:
EXP:-

NDC 6200-764-43
Cetirizine Hydrochloride
Tablet USP, (10 mg)
ANTHISTAMINE
PEAL PUS H
Mfg. By: Granules India Limited
Made in India
LOT:
EXP:-



NDC 62207-764-49

Cetirizine Hydrochloride Tablets, USP 10 mg

Antihistamine

ALLERGY

Indoor & Outdoor Allergies

24 Hour Relief of ■ Sneezing
■ Runny Nose ■ Itchy, Watery Eyes
■ Itchy Throat or Nose

1000 Tablets

Compare to the active ingredient in Zyrtec® Tablets*



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

Drug Facts

Active ingredient (in each tablet) 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

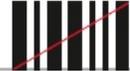
- drowsiness may occur ■ avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

Barcode

Manufactured by:
Granules India Limited
Hyderabad - 500 081, India
MADE IN INDIA
PXXXXXX
M, L, No.: 37/RR/AP/2003/F/R

LOT:
EXP:

Un Varnished Area for
Batch Coding details



PER
HERE

164x64

Drug Facts (continued)

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: Weekdays 9:00 AM to 4:30 PM EST

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

Labeling Format Information

Description	Format
Font Style	Helvetica narrow
Drug Facts title	10 pt, bold italic
Drug Facts (continued)	
Drug Facts (continued)	9 pt, bold italic
Headings	9 pt, regular
Sub Headings	8 pt, bold italic
Leading Text	7 pt, bold
Bullet (solid square)	7 pt.
Bar line	6 pt.
Hair line	1.5 pt.
Alignment	0.75 pt.
	Left

NDC 62207-764-55

Cetirizine Hydrochloride Tablets, USP 10 mg

Antihistamine

ALLERGY

Indoor & Outdoor Allergies



printed foil inner seal on or missing

Ingredients

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

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ itchy, watery eyes ■ sneezing ■ itchy, watery eyes ■ 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.

Barcode

Manufactured by:
Granules India Limited
Hyderabad - 500 081, India
MADE IN INDIA
PXXXXXX
M, L, No.: 37/RR/AP/2003/F/R

LOT:

Un Varnished Area for

24 Hour Relief of ■ Sneezing ■ Runny Nose
 ■ Itchy, Watery Eyes ■ Itchy Throat or Nose

14 Tablets

Compare to the active ingredient in Zyrtec® Tablets*

**Do not use if rim
 bottle is broken**

Drug Facts

Active ingredient
 (in each tablet)
 Cetirizine HCl 10 mg

Uses

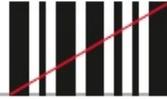
temporarily relieve
 hay fever or other
 allergic symptoms such as:
 ■ runny nose
 ■ itchy or watery eyes

Warnings

Do not use if you have had an allergic
 reaction to this medicine
 or to an antihistamine.

Ask a doctor before use
 if you have kidney disease,
 or if you are taking other
 medicines.

EXP: Batch Coding details



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120 x 42 mm

Drug Facts (continued)

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).

Drug Facts (continued)

Inactive ingredients

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

Questions? call 1-877-770-3183:
 Weekdays 9:00 AM to 4:30 PM EST

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

Labeling Format Information

Description	Format
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Drug Facts title	10 pt. bold italic
Drug Facts (continued)	
Drug Facts (continued)	9 pt. bold italic 9 pt. regular
Headings	8 pt. bold italic
Sub Headings	6 pt. bold
Leading Text	6 pt.
Bullet (solid square)	5 pt.
Bar line	1.5 pt.
Hair line	0.75 pt.
Alignment	Left

CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62207-764
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 2910 (5 MPA.S) (UNII: R75537T0T4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62207-764-55	14 in 1 BOTTLE; Type 0: Not a Combination Product	05/28/2018	
2	NDC:62207-	1000 in 1 BOTTLE; Type 0: Not a Combination	05/28/2018	

4	764-49	Product	05/28/2018	
3	NDC:62207-764-73	13 in 1 CARTON	05/28/2018	
3		10 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	ANDA209274	05/28/2018	

Labeler - Granules India Ltd (915000087)

Establishment

Name	Address	ID/FEI	Business Operations
Granules India Ltd		918609236	manufacture(62207-764)

Revised: 10/2024

Granules India Ltd