CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet, coated
Granules India Ltd

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)

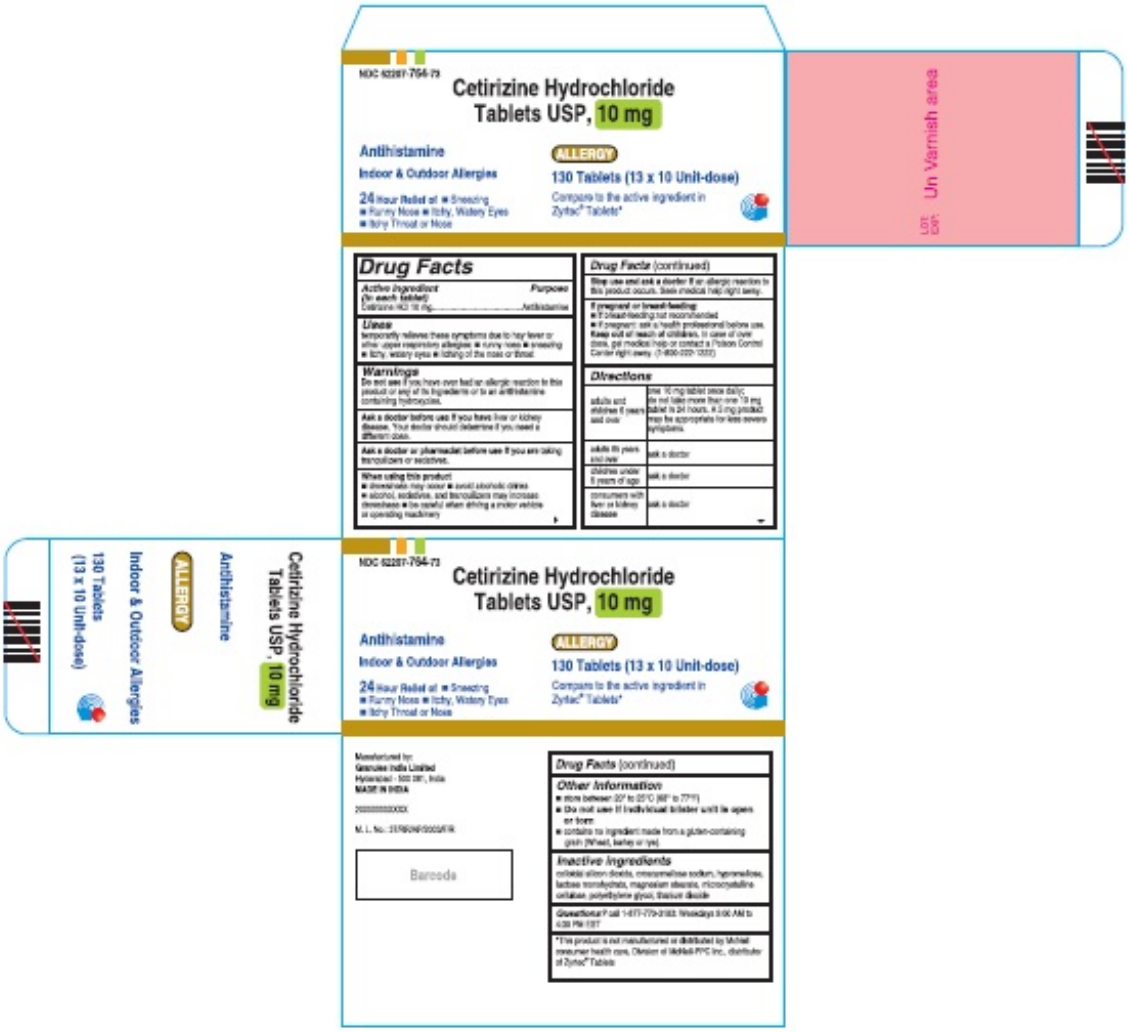
Other information

■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



NDC 62207-764-73

Cetirizine Hydrochloride Tablets USP, 10 mg

Antihistamine

Indoor & Outdoor Allergies

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

ALLERGY

130 Tablets (13 x 10 Unit-dose)

Compare to the active ingredient in Zyrtec® Tablets*

Lot: Exp: Un Varnish area

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

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
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NDC 62207-764-73

Cetirizine Hydrochloride Tablets USP, 10 mg

Antihistamine

Indoor & Outdoor Allergies

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ALLERGY

130 Tablets (13 x 10 Unit-dose)

Compare to the active ingredient in Zyrtec® Tablets*

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

2000000000XX

M. L. No.: 2578GNR/2000/R

Barcode

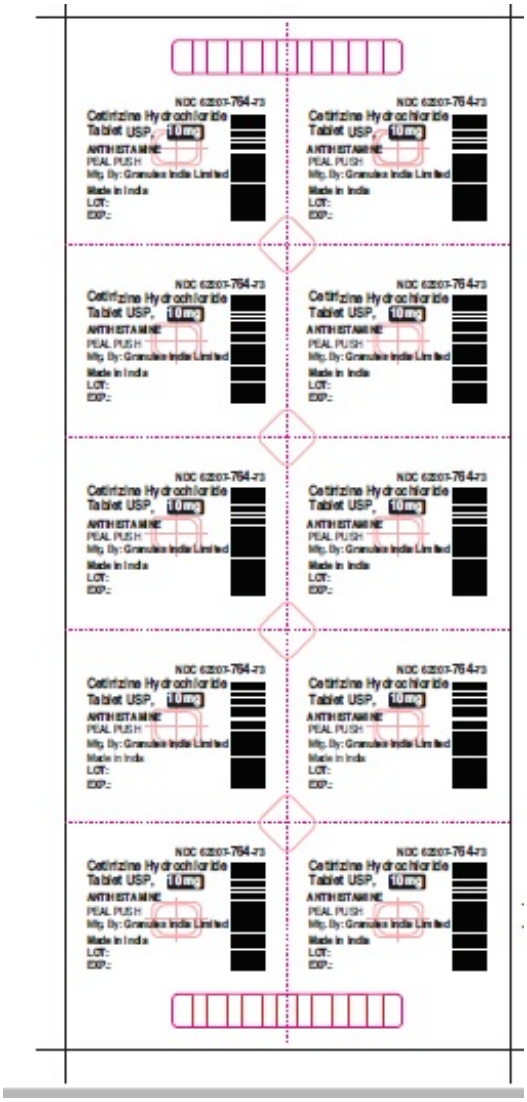
Drug Facts (continued)

Other Information
■ store between 20° to 25°C (68° to 77°F)
■ **Do not use if individual blister unit is open or torn**
■ 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 1-877-779-3183, 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


NDC 62207-764-73
Cetirizine Hydrochloride
Tablet USP, 10mg
ANTIHISTAMINE
PEAL PUSH
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)	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

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

PEEL 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 9 pt. regular
Headings	8 pt. bold italic
Sub Headings	7 pt. bold
Leading Text	7 pt.
Bullet (solid square)	6 pt.
Bar line	1.5 pt.
Hair line	0.75 pt.
Alignment	Left

NDC 62207-764-55

Cetirizine Hydrochloride Tablets, USP 10 mg

Antihistamine ALLERGY

Indoor & Outdoor Allergies

24

do not use if imprinted foil inner seal on or missing

Purpose
Antihistamine

ves these symptoms due to
er upper respiratory allergies:
sneezing ■ itchy, watery eyes
nose or throat

u have ever had an allergic
product or any of its ingredients
amine containing hydroxyzine.

efore use if you have liver or
Your doctor should determine
fferent 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 imp
bottle is broken

Drug Fac

Active ingre
(in each tab
Cetirizine HCl 1(

Uses
temporarily relie
hay fever or oth
■ runny nose ■
■ itching of the

Warnings
Do not use if yo
reaction to this p
or to an antihista

Ask a doctor b
kidney disease.
if you need a dil

EXP.

Batch Coding details

PEEL HERE

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.
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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

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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, 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:62207-764-55	14 in 1 BOTTLE; Type 0: Not a Combination Product	05/28/2018	
2	NDC:62207-764-	1000 in 1 BOTTLE; Type 0: Not a Combination	05/28/2018	

2	49	Product	05/28/2018	

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: 1/2023 Granules India Ltd