CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet, chewable Sun Pharmaceutical Industries, Inc.

Cetirizine Hydrochloride Chewable Tablets

Active ingredient (in each chewable tablet)

For 5 mg:Cetirizine hydrochloride, USP 5 mg

For 10 mg:Cetirizine hydrochloride, USP 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 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.

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

- may be taken with or without water
- chew or crush tablets completely before swallowing

For 5 mg:

adults and children 6 years and over	1 tablet (5 mg) or 2 tablets (10 mg) once daily depending upon severity of symptoms; do not take more than 2 tablets (10mg) in 24 hours.
adults 65 years and over	1 tablet (5 mg) once daily; do not take more than 1 tablet (5 mg) in 24
	hours.
children under 6 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

For 10 mg:

adults and children 6 years and over	Chew and swallow 1 tablet (10 mg) once daily; do not take more than 1 tablet (10 mg) 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)
- do not use if inner safety seal is open or torn
- see top layer for lot number and expiration date

Inactive ingredients

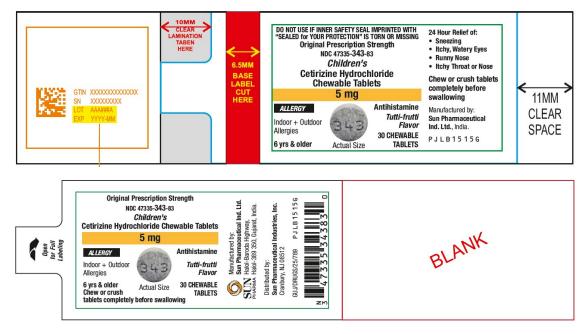
acesulfame potassium, colloidal silicon dioxide, compressible sugar, crospovidone, FD & C Blue No # 2 Aluminum Lake, FD & C Red No # 40 Aluminum Lake, guar gum, magnesium oxide light powder, magnesium stearate, mannitol, microcrystalline cellulose, pregelatinized starch, prosweet N & A flavor powder, talc, tutti frutti flavor

Questions?

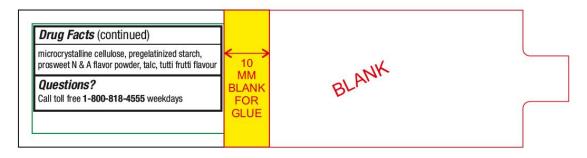
Call toll free 1-800-818-4555 weekdays

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

For 5 mg Allergy: Original Prescription Strength NDC 47335-343-83 Cetirizine Hydrochloride Chewable Tablets 5 mg ALLERGY
Antihistamine
Indoor + Outdoor Allergies
Actual Size
Tutti-frutti Flavor
6 yrs & older
30 CHEWABLE TABLETS
SUN PHARMACEUTICAL INDUSTRIES LTD.

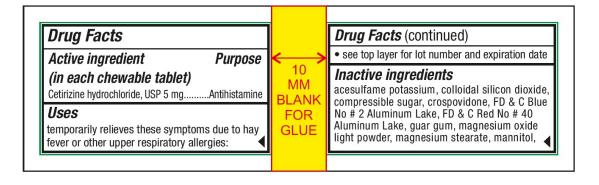


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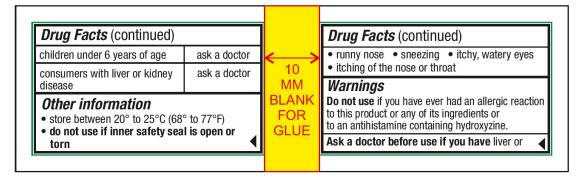
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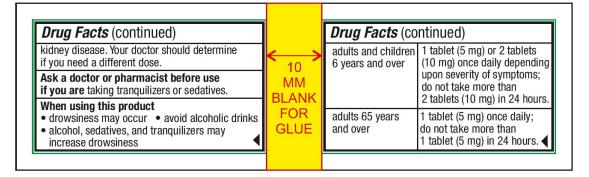
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Drug Facts (continued) Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Directions • may be taken with or without water • chew or crush tablets completely before swallowing

Drug Facts (continued)

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

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

For 10 mg Allergy:
Original Prescription Strength
NDC 47335-344-83
Cetirizine Hydrochloride Chewable Tablets
10 mg
ALLERGY
Antihistamine
Indoor + Outdoor Allergies
Actual Size
Tutti-frutti Flavor
6 yrs & older
30 CHEWABLE TABLETS
SUN PHARMA

DO NOT USE IF INNER SAFETY SEAL IMPRINTED WITH "SEALED for YOUR PROTECTION" IS TORN

24 Hour Relief of:

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

Chew or crush tablets completely before swallowing

Manufactured by: Sun Pharmaceutical Ind. Ltd. Halol-Baroda Highway, Halol-389 350, Gujarat, India.

Original Prescription Strength NDC 47335-344-83

Children's Cetirizine Hydrochloride **Chewable Tablets**

10 mg

ALLERGY

Indoor + Outdoor Allergies

30 CHEWABLE TABLETS



Tutti-frutti Flavor 6 yrs & older

SUN

Antihistamine



Open for Full Labeling -Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512 GUJ/DRUGS/25/789 PJLB1402E

GTIN XXXXXXXXXXXXXXX XXXXXXXX AAA###A

Antihistamine Purpose in each chewable tablet

nay fever or other upper respiratory allergies: temporarily relieves these symptoms due to

runny nose · sneezing · itchy, watery eyes itching of the nose or throat runny nose

Narnings

reaction to this product or any of its ingredients or to Do not use if you have ever had an allergic an antihistamine containing hydroxyzine.

kidney disease. Your doctor should determine if you Ask a doctor before use if you have liver need a different dose

Ask a doctor or pharmacist before use if you are

taking tranquilizers or sedatives. When using this product

 avoid alcoholic drinks alcohol, sedatives, and tranquilizers may increase drowsiness may occur

be careful when driving a motor vehicle or operating machiner) drowsiness

Stop use and ask a doctor if an allergic reaction this product occurs. Seek medical help right away

If pregnant or breast-feeding:

- if breast-feeding: not recommended
- 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) if pregnant: ask a health professional before use.

PJLB1402E

Drug Facts

Drug Facts (continued)

Setirizine hydrochloride, USP Active ingredient

Uses 10 mg..

Chew and swallow 1 tabled (10 mg) once daily; do not

(10 mg) in 24 hours. A 5 mg product may be appropriate for less severe symptoms. ake more than 1 tablet

ask a doctor

ask a doctor ask a doctol consumers with liver or kidney disease adults 65 years children under lears of age and over

Other information

do not use if inner safety seal is open or torn see top layer for lot number and expiration date store between 20° to 25°C (68° to 77°F)

nactive ingredients

Aluminum Lake, guar gum, magnesium oxide light prosweet N & A flavor powder, talc, tutti frutti flavor compressible sugar, crospovidone, FD & C Blue microcrystalline cellulose, pregelatinized starch, acesulfame potassium, colloidal silicon dioxide, No # 2 Aluminum Lake, FD & C Red No # 40 powder, magnesium stearate, mannitol,

HYDROCHLORIDE

Questions?

Call toll free 1-800-818-4555 weekdays

PJLB1402

CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet, chewable

adults and children

years and over

Product Information

chew or crush tablets completely before swallowing

may be taken with or without water

Directions

Product Type HUMAN OTC DRUG Item Code (Source) NDC:47335-343

ORAL **Route of Administration**

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength CETIRIZINE HYDROCHLORIDE (UNII: 640047KTOA) (CETIRIZINE -**CETIRIZ INE**

UNII:YO7261ME24)

Inactive Ingredients

Ingredient Name

Strenath

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SUCROSE (UNII: C151H8M554)	
CROSPOVIDONE (UNII: 2S7830E561)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GUAR GUM (UNII: E8911637KE)	
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 30WL53L36A)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: 08232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics			
Color	PURPLE	Score	no score
Shape	ROUND	Size	8mm
Flavor	TUTTI FRUTTI	Imprint Code	343
Contains			

	Packaging				
# ITEM CODE PACKAGE DESCRIPTION			Marketing End Date		
	NDC:47335-343-	30 in 1 BOTTLE; Type 0: Not a Combination Product	09/09/2011		
	NDC:47335-343-	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/09/2011		

Marketing Information				
Marketing Application Number or Monograph Marketing Start Marketing End Category Citation Date Date				
ANDA	ANDA090142	09/09/2011		

CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet, chewable

Product Information				
Product Type HUMAN OTC DRUG Item Code (Source) NDC:47335-344				
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
CETIRIZINE HYDROCHLORIDE (UNII: 640047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZ INE HYDROCHLORIDE	10 mg		

Inactive Ingredients			
Ingredient Name	Strength		
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
SUCROSE (UNII: C151H8M554)			
CROSPOVIDONE (UNII: 2S7830E561)			
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
GUAR GUM (UNII: E8911637KE)			
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)			

MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 30WL53L36A)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: 08232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics				
Color PURPLE Score no score				
Shape	ROUND	Size	10mm	
Flavor	TUTTI FRUTTI	Imprint Code	344	
Contains				

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47335-344- 83	30 in 1 BOTTLE; Type 0: Not a Combination Product	09/09/2011	
2	NDC:47335-344- 88	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/09/2011	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
ANDA	ANDA090142	09/09/2011			

Labeler - Sun Pharmaceutical Industries, Inc. (146974886)

Establishment				
Name	Address	ID/FEI	Business Operations	
Sun Pharmaceutical Industries Limited		725959238	ANALYSIS(47335-343, 47335-344) , MANUFACTURE(47335-343, 47335-344)	

Revised: 9/2024 Sun Pharmaceutical Industries, Inc.