

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.

 <p>GTIN XXXXXXXXXX SN XXXXXXXX LOT AAAA EXP YYYY-MM</p>	10MM CLEAR LAMINATION TABEN HERE	6.5MM BASE LABEL CUT HERE	<p>DO NOT USE IF INNER SAFETY SEAL IMPRINTED WITH "SEALED for YOUR PROTECTION" IS TORN OR MISSING</p> <p>Original Prescription Strength NDC 47335-343-83</p> <p>Children's Cetirizine Hydrochloride Chewable Tablets</p> <p>5 mg</p> <p>ALLERGY Indoor + Outdoor Allergies 6 yrs & older</p> <p>Actual Size</p> <p>Antihistamine Tutti-frutti Flavor 30 CHEWABLE TABLETS</p> <p>24 Hour Relief of: • Sneezing • Itchy, Watery Eyes • Runny Nose • Itchy Throat or Nose</p> <p>Chew or crush tablets completely before swallowing</p> <p>Manufactured by: Sun Pharmaceutical Ind. Ltd., India. P J L B 1 5 1 5 G</p>	11MM CLEAR SPACE

<p>Original Prescription Strength NDC 47335-343-83</p> <p>Children's Cetirizine Hydrochloride Chewable Tablets</p> <p>5 mg</p> <p>ALLERGY Indoor + Outdoor Allergies 6 yrs & older Chew or crush tablets completely before swallowing</p> <p>Actual Size</p> <p>Antihistamine Tutti-frutti Flavor 30 CHEWABLE TABLETS</p> <p>Manufactured by: Sun Pharmaceutical Ind. Ltd. Hald-Baroda Highway, PHARMA Hald-389 350, Gujarat, India.</p> <p>Distributed by: Sun Pharmaceutical Industries, Inc. Grandway, NJ 08512 GUJDRUGS/25/789 P J L B 1 5 1 5 G</p> <p>47335343830</p>	<p>BLANK</p>
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PAGE 09

<p>Drug Facts (continued)</p> <p>microcrystalline cellulose, pregelatinized starch, prosweet N & A flavor powder, talc, tutti frutti flavour</p> <p>Questions? Call toll free 1-800-818-4555 weekdays</p>	10 MM BLANK FOR GLUE	<p>BLANK</p>
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PAGE 01

PAGE 08

<p>Drug Facts</p> <p>Active ingredient Purpose</p> <p>(in each chewable tablet)</p> <p>Cetirizine hydrochloride, USP 5 mg.....Antihistamine</p> <p>Uses</p> <p>temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:</p>	10 MM BLANK FOR GLUE	<p>Drug Facts (continued)</p> <p>• see top layer for lot number and expiration date</p> <p>Inactive ingredients</p> <p>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,</p>
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Drug Facts (continued)		10 MM BLANK FOR GLUE	Drug Facts (continued)	
children under 6 years of age	ask a doctor		<ul style="list-style-type: none"> • runny nose • sneezing • itchy, watery eyes • itching of the nose or throat 	
consumers with liver or kidney disease	ask a doctor		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	
Other information <ul style="list-style-type: none"> • store between 20° to 25°C (68° to 77°F) • do not use if inner safety seal is open or torn 				

Drug Facts (continued)		10 MM BLANK FOR GLUE	Drug Facts (continued)	
kidney disease. Your doctor should determine if you need a different dose.			adults and children 6 years and over	
Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives. When using this product <ul style="list-style-type: none"> • drowsiness may occur • avoid alcoholic drinks • alcohol, sedatives, and tranquilizers may increase drowsiness 			1 tablet (5 mg) or 2 tablets (10 mg) once daily depending upon severity of symptoms; do not take more than 2 tablets (10 mg) 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.	

Drug Facts (continued)		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)		<ul style="list-style-type: none"> • be careful when driving a motor vehicle or operating machinery 	
Directions <ul style="list-style-type: none"> • may be taken with or without water • chew or crush tablets completely before swallowing 		Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away. If pregnant or breast-feeding: <ul style="list-style-type: none"> • if breast-feeding: not recommended • if pregnant: ask a health professional before use. 	

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 OR MISSING

24 Hour Relief of:

- Sneezing
- 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

Actual Size

Antihistamine
Tutti-frutti Flavor
6 yrs & older





Open for Full Labeling →

Distributed by:
Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512
GUJ/DRUGS/25/789

PJLB1402E



GTIN XXXXXXXXXXXXX
SN XXXXXXXXXXX
LOT AAA##A
EXP YYYY-MM

Drug Facts	Active ingredient Purpose (in each chewable tablet)
	Cetirizine hydrochloride, USP 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)

PJLB1402E

Drug Facts (continued)	Directions
	• may be taken with or without water • chew or crush tablets completely before swallowing
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

PJLB1402E

CETIRIZINE HYDROCHLORIDE		
cetirizine hydrochloride tablet, chewable		
Product Information		
Product Type	HUMAN OTC DRUG	Item Code (Source)
Route of Administration	ORAL	NDC:47335-343
Active Ingredient/Active Moiety		
Ingredient Name		Basis of Strength
CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)		CETIRIZINE HYDROCHLORIDE
		5 mg
Inactive Ingredients		
Ingredient Name		Strength

ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
SUCROSE (UNII: C151H8M554)				
CROSPVIDONE (UNII: 2S7830E561)				
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
GUAR GUM (UNII: E89I1637KE)				
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MANNITOL (UNII: 3OWL53L36A)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
STARCH, CORN (UNII: O8232NY35J)				
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 Start Date	Marketing End Date
1	NDC:47335-343-83	30 in 1 BOTTLE; Type 0: Not a Combination Product	09/09/2011	
2	NDC:47335-343-88	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	

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: 64O047KTOA) (CETIRIZINE - UNII:Y07261ME24)		CETIRIZINE HYDROCHLORIDE	10 mg
Inactive Ingredients			
Ingredient Name			Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
SUCROSE (UNII: C151H8M554)			
CROSPVIDONE (UNII: 2S7830E561)			
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
GUAR GUM (UNII: E89I1637KE)			
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)			

MAGNESIUM STEARATE (UNII: 70097M6I30)				
MANNITOL (UNII: 3OWL53L36A)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
STARCH, CORN (UNII: O8232NY3SJ)				
TALC (UNII: 7SEV7J4R1U)				
Product Characteristics				
Color	PURPLE	Score	no score	
Shape	ROUND	Size	10mm	
Flavor	TUTTI FRUTTI	Imprint Code	344	
Contains				
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.