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 5 mg

For 10 mg:
Cetirizine hydrochloride 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

For 5 mg:

adults and children 6 years and over	1 to 2 tablets once daily depending upon severity of symptoms; do not take more than 2 tablets in 24 hours.
adults 65 years and over	1 tablet once a day; do not take more than 1 tablet 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	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)
- 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

Principal Display Panel

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

HINGE AREA

Drug Facts

Active ingredient (in each chewable tablet) — **Purpose**

Cetirizine hydrochloride, USP 5 mg.....Antihistamine

Uses

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

RESEAL AREA

Label Patent #6,413,604

Drug Facts (continued)

- 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

Insert 1 Top

Drug Facts (continued)

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

Insert 1 Back

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 use.

Insert 2 Top

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

Insert 2 Back

Drug Facts (continued)

adults and children 6 years and over	1 to 2 tablets once daily depending upon severity of symptoms; do not take more than 2 tablets in 24 hours.
adults 65 years and over	1 tablet once a day; do not take more than 1 tablet in 24 hours

Insert 3 Top

Drug Facts (continued)

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

Insert 3 Back

Drug Facts (continued)

- 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,

Insert 4 Top

Drug Facts (continued)

microcrystalline cellulose, pregelatinized starch, prosweet N & A flavor powder, talc, tutti frutti flavor

Questions?

Call toll free **1-800-818-4555** weekdays

Insert 4 Back

24 Hour Relief of:

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

Distributed by:
Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512

PJLB1515D PJLB1515D ISS.08/2014
GUJ/DRUGS/25/789

Batch No.:
Exp.

Open for Full Labeling

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

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

Original Prescription Strength
NDC 47335-343-83
Children's
Cetirizine Hydrochloride Chewable Tablets
5 mg

ALLERGY Antihistamine
Indoor & Outdoor Allergies *Tutti-frutti Flavor*
6 yrs. & older 30 CHEWABLE TABLETS

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

Top Layer

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

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 Antihistamine

Indoor & Outdoor Allergies *Tutti-frutti Flavor*

6 yrs. & older
30 CHEWABLE TABLETS

SUN PHARMA

N 3 47335 34483 7

Open for Full Labeling →

Distributed by:
Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512

PJLB1402C PJLB1402C ISS. 09/2014
GUJ/DRUGS/25/789

Batch No.:

Exp.:

Top Layer [Back side]

Hinge

Drug Facts

Active ingredient (in each chewable tablet) **Purpose**
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)

→ PJLB1402C

Hinge

Base Layer 2 [Front-side]

Hinge

Drug Facts (continued)

Directions • may be taken with or without water

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)
- 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

PJLB1402C

CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:47335-343
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**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)	
CROSPOVIDONE (UNII: 68401960MK)	
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**	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:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	10 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SUCROSE (UNII: C151H8M554)	
CROSPOVIDONE (UNII: 68401960MK)	
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: 10/2018 Sun Pharmaceutical Industries, Inc.