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

relieves itching due to hives (urticaria). This product will not prevent hives or an allergic skin reaction from occurring.

Warnings

Severe Allergy Warning: Get emergency help **immediately** if you have hives along with any of the following symptoms:

- trouble swallowing
- dizziness or loss of consciousness
- swelling of tongue
- swelling in or around mouth
- trouble speaking
- drooling
- wheezing or problems breathing

These symptoms may be signs of anaphylactic shock. This condition can be life threatening if not treated by a health professional **immediately**. Symptoms of anaphylactic shock may occur when hives first appear or up to a few hours later.

Not a Substitute for Epinephrine. If your doctor has prescribed an epinephrine injector for "anaphylaxis" or severe allergy symptoms that could occur with your hives, never use this product as a substitute for the epinephrine injector. If you have been prescribed an epinephrine injector, you should carry it with you at all times.

Do not use

- to **prevent** hives from any known cause such as:

- foods
- insect stings
- medicines
- latex or rubber gloves because this product will not stop hives from occurring. Avoiding the cause of your hives is the only way to prevent them. Hives can sometimes be serious. If you do not know the cause of your hives, see your doctor for a medical exam. Your doctor may be able to help you find a cause.

- 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.
- hives that are an unusual color, look bruised or blistered
- hives that do not itch

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.
- symptoms do not improve after 3 days of treatment
- the hives have lasted more than 6 weeks

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

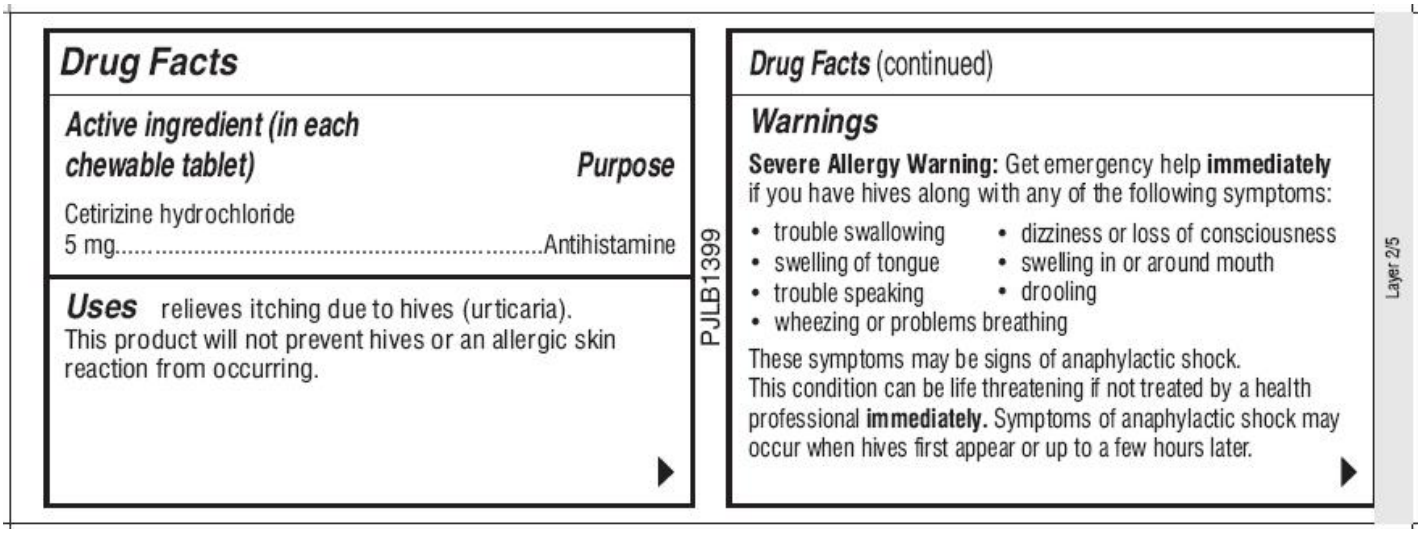
Questions?

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

Principal Display Panel

For 5 mg Hives Relief:
Original Prescription Strength
NDC 47335-343-16
Children's
Cetirizine Hydrochloride Chewable Tablets

5 mg
HIVES Relief
Antihistamine
24 hour *Relief of ITCHING Due to Hives*
Tutti-frutti Flavor
6 yrs. & older
100 CHEWABLE TABLETS
SUN PHARMACEUTICAL INDUSTRIES LTD.



Layer 3/5

Drug Facts (continued)

Not a Substitute for Epinephrine. If your doctor has prescribed an epinephrine injector for "anaphylaxis" or severe allergy symptoms that could occur with your hives, never use this product as a substitute for the epinephrine injector. If you have been prescribed an epinephrine injector, you should carry it with you at all times.

Do not use • to **prevent** hives from any known cause such as:
- foods
- insect stings
- medicines
- latex or rubber gloves because this product will not stop hives from occurring. Avoiding the cause of your hives is the only way to prevent them. Hives can sometimes be serious. If you do not know the cause of your hives, see your doctor for a medical exam. Your doctor may be able to help you find a cause.

PJLB1399

Drug Facts (continued)

- 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.
- hives that are an unusual color, look bruised or blistered
- hives that do not itch

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.
- symptoms do not improve after 3 days of treatment
- the hives have lasted more than 6 weeks

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)

PJLB1399

Drug Facts (continued)

Directions • may be taken with or without water

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

Layer 4/5

Layer 5/5

Drug Facts (continued)

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

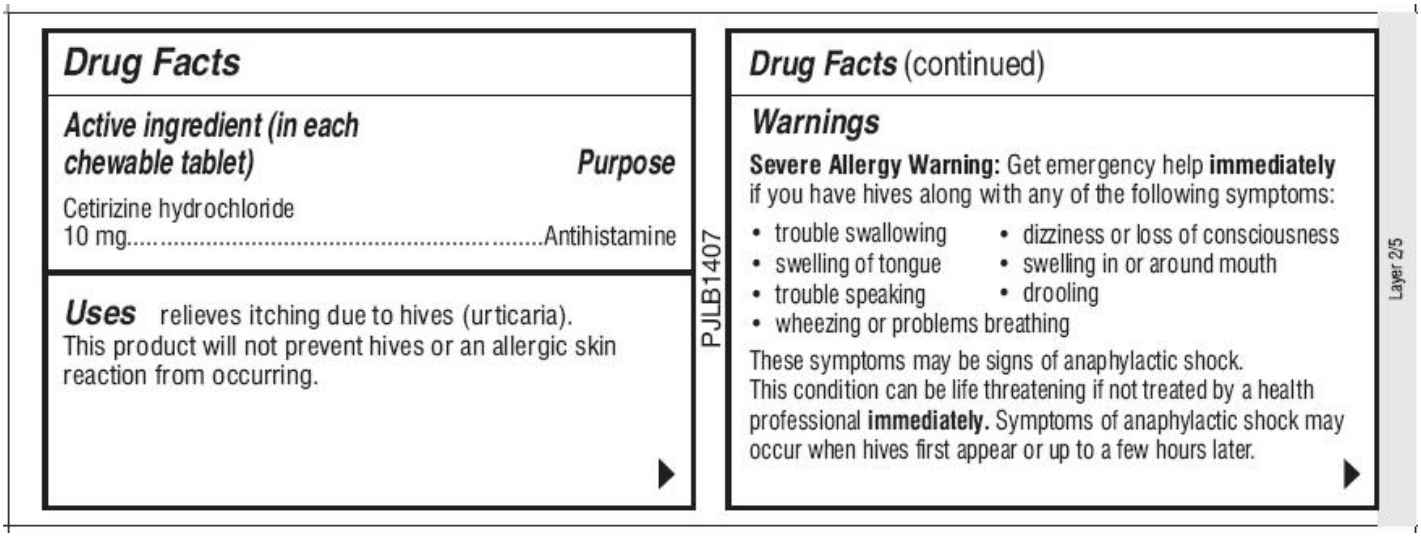
Inactive ingredients acesulfame potassium, colloidal silicon dioxide, compressible sugar, crospovidone, FD & C Blue No # 2 Aluminum Lake, FD & C Red No # 40 Aluminum Lake, guar gum, magnesium oxide light powder, magnesium stearate, mannitol, microcrystalline cellulose, pregelatinized starch, prosweet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

PJLB1399

Drug Facts (continued)

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

For 10 mg Hives Relief:
Original Prescription Strength
NDC 47335-344-16
Children's
Cetirizine Hydrochloride Chewable Tablets
10 mg
HIVES Relief
Antihistamine
Tutti-frutti Flavor
6 yrs. & older
100 CHEWABLE TABLETS
SUN PHARMACEUTICAL INDUSTRIES LTD.



Layer 3/5

Drug Facts (continued)

Not a Substitute for Epinephrine. If your doctor has prescribed an epinephrine injector for "anaphylaxis" or severe allergy symptoms that could occur with your hives, never use this product as a substitute for the epinephrine injector. If you have been prescribed an epinephrine injector, you should carry it with you at all times.

Do not use • to **prevent** hives from any known cause such as:

• foods • insect stings • medicines • latex or rubber gloves because this product will not stop hives from occurring. Avoiding the cause of your hives is the only way to prevent them. Hives can sometimes be serious. If you do not know the cause of your hives, see your doctor for a medical exam. Your doctor may be able to help you find a cause.

PJLB1407

Drug Facts (continued)

• 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.
• hives that are an unusual color, look bruised or blistered
• hives that do not itch

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.
• symptoms do not improve after 3 days of treatment
• the hives have lasted more than 6 weeks

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)

PJLB1407

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

Layer 4/5

Layer 5/5

Drug Facts (continued)

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

PJLB1407

Drug Facts (continued)

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

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:47335-343-15	30 in 1 BOTTLE; Type 0: Not a Combination Product	09/26/2011	
2	NDC:47335-343-16	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/26/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090142	09/26/2011	

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**
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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090142	09/26/2011	

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.