CETIRIZINE HYDROLORIDE ALLERGY - cetirizine hydroloride solution
Caraco Pharmaceutical Laboratories, Ltd

Drug Facts

Active Ingredient (in each 5 mL teaspoonful)

Cetirizine hydrochloride, USP 5mg

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 toll-free number 1-800-222-1222.

Directions

- use only with enclosed dosing cup

adults and children 6 years and over	1 teaspoonful (5 mL) or 2 teaspoonfuls (10 mL) once daily depending upon severity of symptoms; do not take more than 2 teaspoonfuls (10 mL) in 24 hours.
adults 65 years and over	1 teaspoonful (5 mL) once daily; do not take more than 1 teaspoonful (5 mL) in 24 hours.
children 2 to under 6 years of age	½ teaspoonful (2.5 mL) once daily. If needed, dose can be increased to a maximum of 1 teaspoonful (5 mL) once daily or ½ teaspoonful (2.5 mL) every 12 hours. Do not give more than 1 teaspoonful (5 mL) in 24 hours.
children under 2 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

Other information

Store between 20 to 25ºC (68 to 77ºF) or store refrigerated, 2 to 8ºC (36 to 46ºF)

Inactive ingredients

artificial grape flavor, glacial acetic acid, glycerin, methylparaben, purified water, propylene glycol, propylparaben, sodium acetate, and sucrose

Questions or comments?

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

Dosing Cup Included

Dosing cup should be washed and left to air dry after each use.

Do not use if carton is opened, or if seal on bottle is broken or missing.

Dist. by: **Caraco Pharmaceutical Laboratories, Ltd.**

Detroit, Michigan 48202

Mfg. by: **SUN Pharmaceutical Industries, Inc.**

Bryan, Ohio 43506

6028L01 Iss: 09/11

Principal Display Panel

NDC 57664-263-31

2 years & older

Children's

Cetirizine

Hydrochloride

1mg / mL Oral Solution, USP

antihistamine

ALLERGY

Indoor and Outdoor Allergies

24 Hour Relief of

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

Dosing Cup Included

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2 years and older

Grape Syrup

4 fl. oz. (120 mL)

NDC 57664-263-31

2 years & older

Children's

Cetirizine Hydrochloride Oral Solution, USP

1 mg/mL

antihistamine

ALLERGY

Indoor and Outdoor Allergies

24 Hour Relief of: • *Sneezing* • *Runny Nose* • *Itchy, Watery Eyes* • *Itchy Throat or Nose*

Dosing Cup Included

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2 years and older
Grape Syrup

4 fl. oz. (120 mL) SUN PHARMACEUTICAL INDUSTRIES, INC.

NDC 57664-263-31

2 years & older

Children's

Cetirizine Hydrochloride Oral Solution, USP

1 mg/mL

antihistamine

ALLERGY

Indoor and Outdoor Allergies

24 Hour Relief of: • *Sneezing* • *Runny Nose* • *Itchy, Watery Eyes* • *Itchy Throat or Nose*

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2 years and older
Grape Syrup

4 fl. oz. (120 mL) SUN PHARMACEUTICAL INDUSTRIES, INC.

Children's

2 years & older

Cetirizine Hydrochloride

ALLERGY

Oral Solution, USP 1 mg/mL

antihistamine

Indoor and Outdoor Allergies

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Drug Facts (continued)

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Bryan, Ohio 43506

N3 57664 26331 0

6028L01 Iss: 09/11

CETIRIZINE HYDROLORIDE ALLERGY

cetirizine hydroloride solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:57664-263
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	1 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ACETIC ACID (UNII: Q40Q9N063P)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM ACETATE (UNII: 4550K0SC9B)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics			
Color	YELLOW (Colorless to slightly yellow)	**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:57664-263-31	120 mL in 1 BOTTLE		
2	NDC:57664-263-34	470 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091327	12/01/2011	

Labeler - Caraco Pharmaceutical Laboratories, Ltd (146974886)

Registrant - Sun Pharmaceutical Industries Inc. (621283733)

Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharmaceutical Industries Inc.		621283733	MANUFACTURE, ANALYSIS

Revised: 10/2011 Caraco Pharmaceutical Laboratories, Ltd