CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride solution
Lannett Company, Inc.

Cetirizine Hydrochloride Oral Solution - Allergy

Drug Facts

Active ingredient (in each 5 mL (teaspoonful(tsp)): Cetirizine HCl 5 mg

Purpose: Antihistamine

Uses

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

- runny nose
- itchy, watery eyes
- sneezing
- 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)

Directions

use only with enclosed dosing cup

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

Inactive ingredients

calcium acetate, grape flavor, glacial acetic acid, glycerin, methylparaben, propylene glycol, propylparaben, purified water.

Questions?

Call 1-888-974-5279

Cetirizine Hydrochloride Oral Solution - Hives Relief

Drug Facts

Active ingredient (in each 5 mL (teaspoonful)): Cetirizine HCl 5 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 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 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.

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 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)

Inactive ingredients

calcium acetate, grape flavor, glacial acetic acid, glycerin, methylparaben, propylene glycol, propylparaben, purified water

Questions?

Call 1-888-974-5279

Dosing Cup Included

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

Do not use if carton is open; or if safety seal printed with “SEALED FOR YOUR PROTECTION” around cap of the bottle is broken or missing.

SAVE THIS CARTON FOR FULL LABELING INFORMATION

Control No. Exp. Date

Children's
Cetirizine Hydrochloride 1 mg/mL Oral Solution

Drug Facts

Active ingredient (in each 5 mL (teaspoonful (tsp)) — **Purpose**
Cetirizine HCl 5 mg — Antihistamine

Uses
temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
- runny nose
- itchy watery eyes
- sneezing
- 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)

Directions ■ use only with enclosed dosing cup

adults and children 6 years and over	1 teaspoonful (tsp) (5 mL) or 2 teaspoonfuls (tsp) (10 mL) once daily, decreasing upon severity of symptoms; do not take more than 2 teaspoonfuls (tsp) (10 mL) in 24 hours
adults 65 years and over	1 teaspoonful (tsp) (5 mL) once daily; do not take more than 1 teaspoonful (tsp) (5 mL) in 24 hours
children 2 to under 6 years of age	½ teaspoonful (tsp) (2.5 mL) once daily; if needed, dose can be increased to a maximum of 1 teaspoonful (tsp) (5 mL) once daily or ½ teaspoonful (tsp) (2.5 mL) every 12 hours. Do not give more than 1 teaspoonful (tsp) (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 25°C (68° to 77°F)

Inactive ingredients
sodium acetate, grape flavor, glacial acetic acid, glycerin, methylparaben, propylene glycol, propylparaben, purified water

Questions? 1-888-374-5279

SILARX

NDC 54838-552-40

Children's
Cetirizine Hydrochloride 1 mg/mL Oral Solution

Allergy

Antihistamine
Indoor & Outdoor Allergies
Alcohol Free/Sugar Free

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

Do not use if carton is open; or if safety seal printed with "SEALED FOR YOUR PROTECTION" around cap of the bottle is broken or missing.

SAVE THIS CARTON FOR FULL LABELING INFORMATION

See bottom or top flap of the carton for Control # and Exp. Date.

Manufactured by:
Silarx Pharmaceuticals, Inc.
1033 Stoneleigh Ave., Carmel, NY 10512

Rev. 09/13

SILARX

NDC 54838-552-40

Children's
Cetirizine Hydrochloride 1 mg/mL Oral Solution

Allergy

Antihistamine
Indoor & Outdoor Allergies
Alcohol Free/Sugar Free

24 hour Relief of:
- *Sneezing*
- *Runny Nose*
- *Itchy, Watery Eyes*
- *Itchy Throat or Nose*

2 yrs. & older
Grape Flavor

Dosing Cup Included

120 mL (4 FL OZ)

SILARX

NDC 54838-552-40

Children's
Cetirizine Hydrochloride 1 mg/mL Oral Solution

Allergy

Antihistamine
Indoor & Outdoor Allergies
Alcohol Free/Sugar Free

24 hour Relief of:
- *Sneezing*
- *Runny Nose*
- *Itchy, Watery Eyes*
- *Itchy Throat or Nose*

2 yrs. & older
Grape Flavor

Dosing Cup Included

120 mL (4 FL OZ)

CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54838-552

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 in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CALCIUM ACETATE (UNII: Y882YXF34X)	
ACETIC ACID (UNII: Q40Q9N063P)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	GRAPE (Grape Flavor)	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:54838-552-40	120 mL in 1 CARTON; Type 0: Not a Combination Product	05/02/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091130	05/02/2011	

CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54838-559
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 in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CALCIUM ACETATE (UNII: Y882YXF34X)	
ACETIC ACID (UNII: Q40Q9N063P)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	GRAPE (Grape Flavor)	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:54838-559-40	120 mL in 1 CARTON; Type 0: Not a Combination Product	05/06/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091130	05/06/2011	

Labeler - Lannett Company, Inc. (161630033)

Revised: 9/2013 Lannett Company, Inc.