

CETIRIZINE HYDROCHLORIDE - cetirizine hydrochloride solution
Silarx Pharmaceuticals, 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 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

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**



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



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)



NDC 54838-552-40

**Children's
Cetirizine
Hydrochloride
1 mg/mL
Oral Solution**

Allergy

**Antihistamine
Indoor & Outdoor Allergies
Alcohol Free/Sugar Free**

**24 hour
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**2 yrs.
& older
Grape Flavor**

Dosing Cup Included

120 mL (4 FL OZ)

Drug Facts

Active ingredient Purpose
(In each 5 mL (teaspoonful (tsp)))
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
• Avoid alcohol while using this product.
• Avoid grapefruit juice while using this product.
• 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, call 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 (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: 5 teaspoonfuls (2.5 mL) once daily. If needed, dose can be increased to a maximum of 1 teaspoonful (5 mL) once daily or 1/2 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 25°C (68° to 77°F).

Inactive ingredients
sodium acetate, grape-flavor, grape-flavor acid, glycerin, methylparaben, propylene glycol, propylparaben, purified water.

Questions? ☎ 1-800-374-5274



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Control No. Exp. Date

**Children's
Cetirizine
Hydrochloride
1 mg/mL
Oral Solution**



NDC 54838-559-40

**Children's
Cetirizine
Hydrochloride
1 mg/mL
Oral Solution**

Hives Relief



NDC 54838-559-40

**Children's
Cetirizine
Hydrochloride
1 mg/mL
Oral Solution**

Hives Relief



NDC 54838-559-40

**Children's
Cetirizine
Hydrochloride
1 mg/mL
Oral Solution**

Hives Relief

Drug Facts

Active Ingredient
(in each 5 mL (teaspoonful) (tsp))
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 professionals 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, sodatives 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 5 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.

Drug Facts (continued)

Directions ■ use only with enclosed dosing cup

adults and children 6 years and over 1 teaspoonful (5 mL) or 2 teaspoonful (10 mL) once daily depending upon severity of symptoms; do not take more than 2 teaspoonful (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? ☎ 1-888-974-5278

Manufactured by
Silarx Pharmaceuticals, Inc.
78 West Street, Spring Valley, NY 10977, USA Rev. 07/12

Antihistamine
Alcohol Free/Sugar Free

**24 hour
Relief of:
ITCHING
Due to Hives**

**6 yrs.
& older
Grape Flavor**

Dosing Cup Included

120 mL (4 FL OZ)

Antihistamine
Alcohol Free/Sugar Free

Dosing Cup Included

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

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SAVE THIS CARTON FOR FULL LABELING INFORMATION

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



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CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride solution

Product Information

Product Type

HUMAN OTC DRUG LABEL

Item Code (Source)

NDC:54838-552

Route of Administration

ORAL

DEA Schedule

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Cetirizine Hydrochloride (Cetirizine)	Cetirizine Hydrochloride	5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
calcium acetate	
acetic acid	
glycerin	
methylparaben	
propylene glycol	
propylparaben	
water	

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		

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 LABEL	Item Code (Source)	NDC:54838-559
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Cetirizine Hydrochloride (Cetirizine)	Cetirizine Hydrochloride	5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
calcium acetate	
acetic acid	
glycerin	
methylparaben	
propylene glycol	
propylparaben	
water	

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		

Marketing Information

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

Labeler - Silarx Pharmaceuticals, Inc (161630033)