

**CHILDRENS CETIRIZINE HYDROCHLORIDE HIVES RELIEF - cetirizine hydrochloride solution**  
**Aurohealth LLC**

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**Drug Facts**

**Active ingredient (in each 5 mL)**

Cetirizine hydrochloride USP 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 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 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)

**Directions**

- use only with enclosed dosing cup
- find right dose on chart below
- mL = milliliter

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)
- **Do not use if carton is opened, or if cap safety seal is broken or missing.**

### Inactive ingredients

cherry mint flavor, glacial acetic acid, glycerin, methylparaben, propylene glycol, propylparaben, purified water, sodium acetate trihydrate, sucrose

### Questions?

call **1-855-274-4122**

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

**Do not use if carton is opened, or if cap safety seal is broken or missing.**

Manufactured for:

**AUROHEALTH LLC,**  
2572 Brunswick Pike,  
Lawrenceville, NJ 08648

Manufactured by:

**Aurobindo Pharma Limited**  
Hyderabad-500 090, India

M.L.No.: 19/HD/AP/95/F/R

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 1 mg/mL (120 mL Bottle)**

**AUROHEALTH**

**NDC 58602-030-24**

***Children's***

**Cetirizine Hydrochloride**

**Oral Solution USP**

**1 mg/mL**

**antihistamine**

***HIVES  
Relief***

**24 hour**

**Relief of**

**ITCHING**

**Due to Hives**

***6 yrs.***

***& older***

**Dye-Free**

**Cherry Flavor**

**4 fl oz (120 mL)**

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

Do not use if the cap safety seal is broken or missing.



LOT EXP

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3001000263

 **AUROHEALTH**

NDC 58602-030-24

*Children's*

**Cetirizine Hydrochloride  
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**24** hour  
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**4 fl oz (120 mL)**

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Lift Here

**Drug Facts**

**Active ingredient  
(in each 5 mL)**

**Purpose**

Cetirizine hydrochloride USP 5 mg...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.



Pattern denotes LOT/EXP area  
- NO VARNISH - NO COPY  
- NO BACKGROUND COLOR

Top ply (Back)

**Drug Facts (continued)**

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

**Drug Facts (continued)**

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 (1-800-222-1222). **Directions** use only with enclosed dosing cup. mL = milliliter. 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). **Do not use if the cap safety seal is broken or missing.** **Inactive ingredients** cherry mint flavor, glacial acetic acid, glycerin, methylparaben, propylene glycol, propylparaben.

**Drug Facts (continued)**

purified water, sodium acetate trihydrate, sucrose  
**Questions ? call 1-855-274-4122**

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 1 mg/mL Carton (120 mL)**

**AUROHEALTH**  
**NDC 58602-030-24**  
*Children's*  
**Cetirizine Hydrochloride**  
**Oral Solution USP**  
**1 mg/mL**  
**antihistamine**

**HIVES  
Relief**

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

**6 yrs.  
& older**  
**Dye-Free**  
**Cherry Flavor**  
**4 fl oz (120 mL)**  
**Dosing Cup Included**

No Coating Area

3002000142



3002000142

**Drug Facts**

**Active Ingredient** *Purpose*  
(in each 5 mL)  
Cetirizine hydrochloride USP 5 mg.....Antihistamine

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

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 ■ trouble swallowing ■ dizziness or loss of consciousness  
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■ 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 ▶

**Drug Facts (continued)**

■ 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**

■ use only with enclosed dosing cup  
 ■ find right dose on chart below  
 ■ mL = milliliter

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children under 6 years of age ask a doctor

consumers with liver or kidney disease ask a doctor

**Other Information**

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**Inactive Ingredients** cherry mint flavor, glacial acetic acid, glycerin, methylparaben, propylene glycol, propylparaben, purified water, sodium acetate trihydrate, sucrose

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



NDC 58602-030-24

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**1 mg/mL**  
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**24**  
 hour  
**Relief of**  
**ITCHING**  
**Due to Hives**

6 yrs. & older

**Cherry**  
**Flavor**

**Dye-Free**



**4 fl oz (120 mL)**

**Dosing Cup**  
**Included**



NDC 58602-030-24

**Children's**  
**Cetirizine Hydrochloride**  
**Oral Solution USP**  
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 antihistamine



**24**  
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**Cherry**  
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**4 fl oz (120 mL)**

**Dosing Cup**  
**Included**

No Coating Area

3002000142



N 3 58602 03024 17

LOT  
 EXP

N.C.  
 Area

# CHILDRENS CETIRIZINE HYDROCHLORIDE HIVES RELIEF

cetirizine hydrochloride solution

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58602-030
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CETIRIZINE HYDROCHLORIDE</b> (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	1 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>ACETIC ACID</b> (UNII: Q40Q9N063P)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM ACETATE</b> (UNII: 4550K05C9B)	
<b>SUCROSE</b> (UNII: C151H8M554)	

## Product Characteristics

<b>Color</b>	YELLOW (Colorless to Pale Yellow)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY (Cherry Mint)	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-030-24	1 in 1 CARTON	06/24/2015	
1		120 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
2	NDC:58602-030-20	1 in 1 CARTON	06/24/2015	
2		240 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
3	NDC:58602-030-26	480 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package	06/24/2015	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090750	06/24/2015	

**Labeler** - Aurohealth LLC (078728447)

## Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		918917642	ANALYSIS(58602-030) , MANUFACTURE(58602-030)

Revised: 11/2022

Aurohealth LLC