

CHILDRENS CETIRIZINE HYDROCHLORIDE HIVES RELIEF - cetirizine hydrochloride solution
Aurohealth LLC

Drug Facts

Active ingredient (in each 5 mL)

Cetirizine hydrochloride USP 5 mg

Purpose

Antihistamine

Uses

reduces hives and 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	5 mL or 10 mL once daily depending upon severity of symptoms; do not take more than 10 mL in 24 hours.
adults 65 years and over	5 mL once daily; do not take more than 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**
(Monday - Friday 8:30 AM to 5:00 PM EST)

Distributed by:
AUROHEALTH LLC
279 Princeton-Hightstown Road
East Windsor, NJ 08520

Made in India

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	Reduces Itching Due to Hives	Reduces Hives
6 yrs & older		

4 fl oz (120 mL)

Cherry Flavor

AUROHEALTH NDC 58602-030-24

Children's
Cetirizine Hydrochloride
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Uses reduces hives and 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

Purpose

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

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P1435835

*
 Unvarnished Zone
 (dotted line not for printing)
 42 x 15 mm

*Lot: XXXXXXXX
 Exp.: YYYY-MMM
 Prefix, Variables of Lot, Exp and Neutral code shall be printed online during packing.

Top ply (Back)

Gluing Area

Drug Facts (continued)
 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.

Drug Facts (continued)
 ■ 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:** 5 mL or 10 mL

Drug Facts (continued)
 once daily depending upon severity of symptoms; do not take more than 10 mL in 24 hours. **Adults 65 years and over:** 5 mL once daily; do not take more than 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, purified water, sodium acetate trihydrate, sucrose **Questions ?** call 1-855-274-4122 (Monday – Friday 8:30 AM to 5:00 PM EST)

P1435835

Hinge/NV Area

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

AUROHEALTH

NDC 58602-030-24

***Compare to the active ingredient in Children's ZYRTEC®**

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

Hives

**Relief
6 yrs &
older**

HIVES RELIEF

**24 Hour relief
Reduces Itching
Due to Hives**

**Reduces
Hives**

Cherry Flavor

4 fl oz (120 mL)

Dosing cup
included



Important: Read all product information before using.
Keep this box for important information.

Drug Facts

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

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Drug Facts (continued)

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 ■ 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
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 ■ find right dose on chart below ■ mL = milliliter
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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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 279 Princeton-Hightstown Road
 East Windsor, NJ 08520

Made in India

*This product is not manufactured or distributed by Johnson and Johnson Consumer Inc., Monell Consumer Healthcare Division, distributor of Children's Zyrtec®

AUROHEALTH

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

antihistamine

AUROHEALTH

NDC 58602-030-24

*Compare to the active ingredient in Children's Zyrtec®

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

antihistamine

Hives Relief

6 yrs & older

HIVES RELIEF

24 Hour relief



Cherry Flavor

4 fl oz (120 mL)



Dosing cup included

AUROHEALTH

NDC 58602-030-24

*Compare to the active ingredient in Children's Zyrtec®

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

antihistamine

HIVES RELIEF

24 Hour relief



Cherry Flavor

4 fl oz (120 mL)



Dosing cup included



P1058286

Unvarnished Zone
 (dotted line not for printing)
 48 x 19 mm

*Lot: XXXXXXXX
 Exp.: YYYY-MMM
 Prefix, Variables of Lot, Exp and Neutral code shall be printed online during packing.

CHILDRENS CETIRIZINE HYDROCHLORIDE HIVES RELIEF
 cetirizine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-030
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)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM ACETATE (UNII: 4550K0SC9B)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

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

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: 12/2025

Aurohealth LLC