

CETIRIZINE HYDROCHLORIDE (HIVES RELIEF) - cetirizine hydrochloride capsule
Aurohealth LLC

Cetirizine HCl Capsules 10 mg (Hives Relief)

Drug Facts

Active ingredient (in each capsule)

Cetirizine HCl USP 10 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

adults and children 6 years and over	one 10 mg capsule once daily; do not take more than one 10 mg capsule in 24 hours. A 5 mg product may be appropriate for less severe symptoms.
adults 65 years and over	ask a doctor
children under 6 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

Other information

- store between 20° - 25°C (68° - 77°F)
- avoid high humidity and excessive heat above 40°C (104°F)
- protect from light
- do not use if seal imprinted with SEALED for YOUR PROTECTION under the bottle cap is broken or missing.

Inactive ingredients

black iron oxide, gelatin, glycerin, hypromellose, polyethylene glycol, propylene glycol, purified water, sodium hydroxide, sorbitol sorbitan solution

Questions or comments?

call 1-855-274-4122 (Monday - Friday 8:30 AM to 5:00 PM EST)

Distributed by:

AUROHEALTH LLC
2572 Brunswick Pike
Lawrenceville, NJ 08648

Made in India

Code: TS/DRUGS/22/2009

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 10 mg (12's Capsule Container Label)

HIVES Relief NDC 58602-808-04
Original Prescription Strength

Cetirizine HCl Capsules

10 mg CZ10
Antihistamine (Actual Size)

**READ AND KEEP THE OUTER PACKAGE FOR
COMPLETE WARNINGS AND INFORMATION**

12 LIQUID GELS*

*** LIQUID-FILLED CAPSULES**

AUROHEALTH

Base Label



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<p>Drug Facts (continued)</p> <p>Uses relieves itching due to hives (urticaria). This product will not prevent hives or an allergic skin reaction from occurring.</p> <p>Warnings</p> <p>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 of or around mouth, trouble speaking, drooping, swelling or problems breathing.</p>	<p>Drug Facts (continued)</p> <p>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</p>	<p>Drug Facts (continued)</p> <p>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.</p>	<p>Drug Facts (continued)</p> <p>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 heart or kidney disease. Your doctor should determine if you need a different dose. Hives that are an unusual color, look banded or distorted, 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</p>
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front

<p>Drug Facts (continued)</p> <p>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</p>	<p>Drug Facts (continued)</p> <p>Control Center right away. (1-800-222-1222) Directions Adults and children 6 years and over: One 10 mg capsule twice daily; do not take more than one 10 mg capsule in 24 hours. A 5 mg product may be appropriate for less severe symptoms. Adults 65 years and over: ask a doctor. Children under 6 years of age: ask a doctor. Consumers with liver or kidney disease: ask a doctor. Other information store between 20° - 25°C (68° - 77°F); avoid high humidity and excessive</p>	<p>Drug Facts (continued)</p> <p>heat above 40°C (104°F) product from light. do not use if seal imprinted with SEALED for YOUR PROTECTION under the bottle cap is broken or missing. inactive ingredients black iron oxide, guaiin, glycerin, hypromellose, polyethylene glycol, propylene glycol, purified water, sodium hydroxide, sorbitol sorbitan solution. Questions or comments? call 1-855-274-4122 (Monday - Friday 8:30 AM to 5:00 PM EST)</p>	<p>HIVES Relief Original Prescription Strength Cetrizine HCl Capsules 10 mg Antihistamine READ AND KEEP THE OUTER PACKAGE FOR COMPLETE WARNINGS AND INFORMATION AUROHEALTH</p> <p>Do not use if seal imprinted with SEALED for YOUR PROTECTION under the bottle cap is broken or missing.</p> <p>Drug Facts</p> <p>Active ingredient (in each capsule) Cetirizine HCl USP 10 mg</p> <p>Purpose Antihistamine</p>
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PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 10 mg (12's Capsule Container Carton Label)

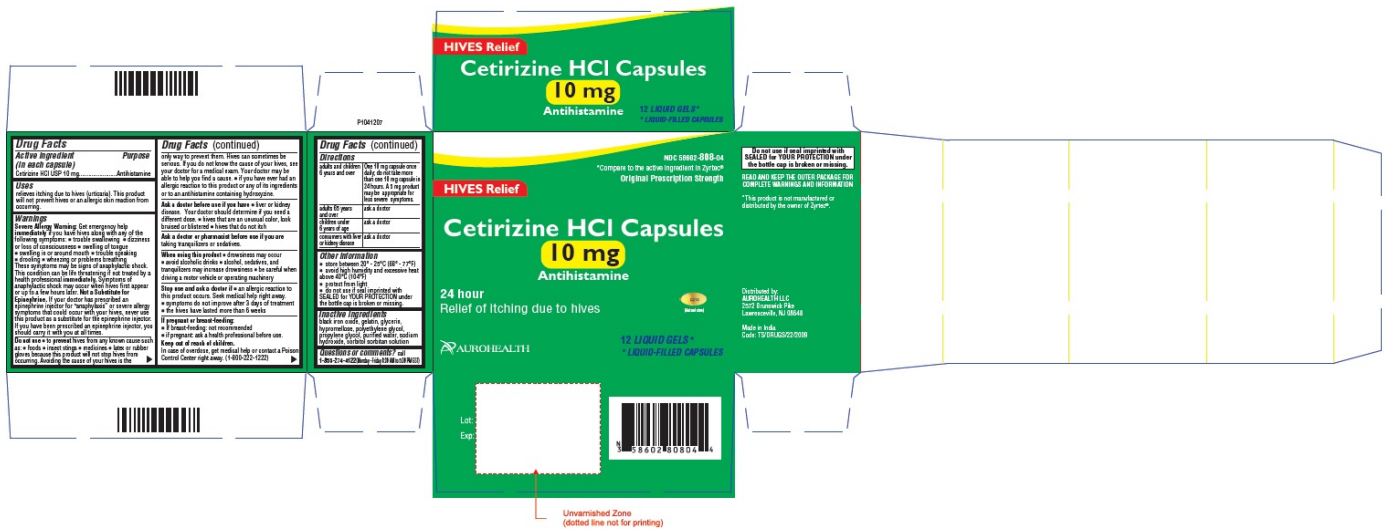
NDC 58602-808-04

*Compare to the active ingredient in Zyrtec®
Original Prescription Strength
HIVES Relief

Cetirizine HCl Capsules
10 mg
Antihistamine

24 hour Relief of itching due to hives
CZ10 (Actual Size)

12 LIQUID GELS*
* LIQUID-FILLED CAPSULES
AUROHEALTH



CETIRIZINE HYDROCHLORIDE (HIVES RELIEF)

cetirizine hydrochloride capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-808
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETIRIZINE HYDROCHLORIDE (UNII: 640047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSE 2910 (6 MPAS) (UNII: 0WZ8WG20P6)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	YELLOW (Clear colourless to pale yellow viscous liquid)	Score	no score
Shape	OVAL	Size	13mm
Flavor		Imprint Code	CZ10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-808-04	1 in 1 CARTON	07/20/2018	
1		12 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-808-53	1 in 1 CARTON	07/20/2018	
2		25 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58602-808-12	1 in 1 CARTON	07/20/2018	
3		40 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:58602-808-16	65 in 1 CARTON	07/20/2018	
4		65 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209107	07/20/2018	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	ANALYSIS(58602-808) , MANUFACTURE(58602-808)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(58602-808) , MANUFACTURE(58602-808)

Revised: 9/2020

Aurohealth LLC