

**CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride solution**  
**BAJAJ MEDICAL, LLC**

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**HIVES**

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

**1 mg/mL**

**6 yrs. & older**

***Drug Facts***

***Active Ingredient (in each 5 mL teaspoonful)***

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**

**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**

**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 toll-free number 1-800-222-1222.

**Directions**

- use with a 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.
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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) or store refrigerated, 2 to 8°C (36 to 46°F)

### **Inactive ingredients**

glacial acetic acid, glycerin, grape flavor, methylparaben, propylene glycol, propylparaben, purified water, sodium acetate, and sucrose

### **Questions or comments?**

call toll-free **1-800-581-2528** weekdays

### **PRINCIPAL DISPLAY PANEL:**

**4 fl. oz. (120 mL) - NDC 61037-480-22**

**NDC 61037-480-22**

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

*6 yrs. & older*

### **Antihistamine**

Grape Flavored

### **HIVES Relief**

### **24 hour Relief of ITCHING**

*Due to Hives*

**4 fl. oz. (120 mL)**

Dosing cup should be washed and left to air dry after each use. Do not use if seal on bottle is broken or missing.

### **Manufactured by:**

Bajaj Medical, LLC  
Chicago IL 60609, USA

**Issued:** 06/2025



Base label without leaflet



Base label with leaflet

**Drug Facts** (continued)

**Warnings**  
**Severe Allergy Warning:** Get emergency help immediately if you have hives along with any of the following symptoms:

- trouble swallowing
- trouble breathing
- trouble speaking
- wheezing or problems breathing
- dizziness or loss of consciousness
- swelling in or around mouth
- drooling

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.

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**Drug Facts** (continued)

**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.**

**Drug Facts** (continued)

**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 toll-free number 1-800-222-1222.

**Drug Facts** (continued)

**Directions** • use with a 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) or store refrigerated, 2 to 8°C (36 to 46°F)

**Drug Facts** (continued)

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

**Questions or comments?**  
 call toll-free 1-800-581-2528 weekdays

Manufactured by:  
 Bajaj Medical, LLC  
 Chicago IL 60609, USA  
 Issued: 06/2025

**PRINCIPAL DISPLAY PANEL:**  
**16 fl. oz. (480 mL) - NDC 61037-480-23**  
**NDC 61037-480-23**

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

*6 yrs. & older*

**Antihistamine**

Grape Flavored

**HIVES Relief**

**24 hour Relief of ITCHING**

*Due to Hives*

**16 fl. oz. (480 mL)**

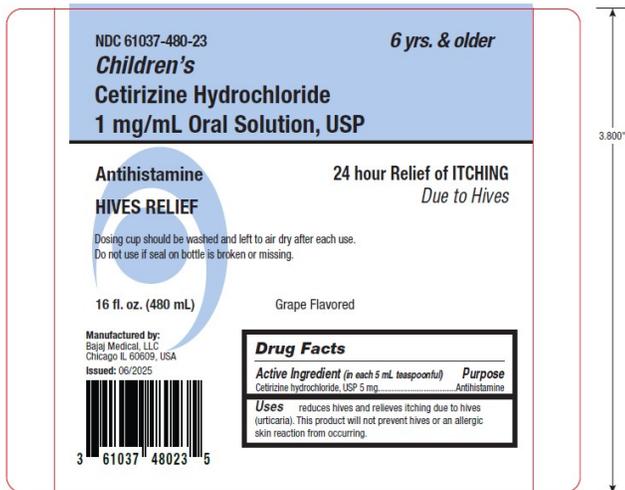
Dosing cup should be washed and left to air dry after each use. Do not use if seal on bottle is broken or missing.

**Manufactured by:**

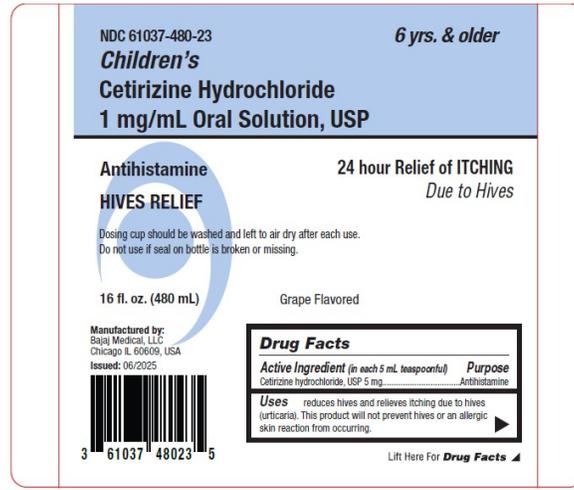
Bajaj Medical, LLC

Chicago IL 60609, USA

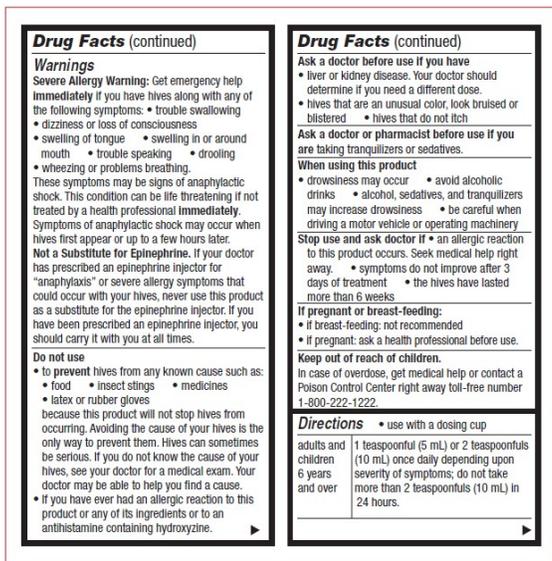
**Issued: 06/2025**



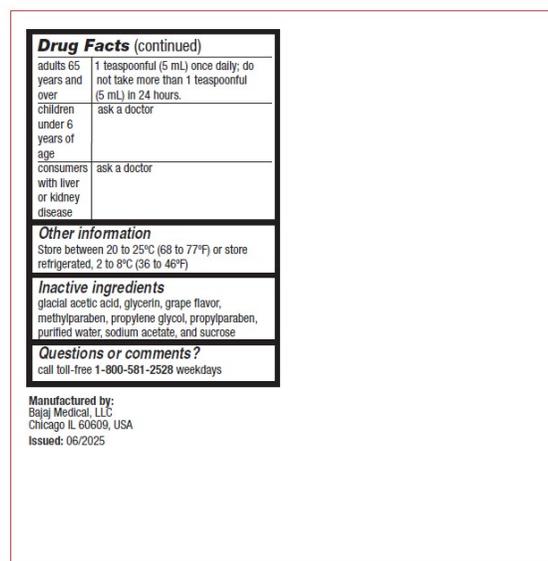
Base label without leaflet



Base label with leaflet



Leaflet Panel #1



Leaflet Panel #2

**PRINCIPAL DISPLAY PANEL:**  
**8 fl. oz. (240 mL) - NDC 61037-480-24**  
**NDC 61037-480-24**  
**Children's Cetirizine Hydrochloride Oral Solution, USP**  
**1 mg/mL**  
**6 yrs. & older**  
**Antihistamine**  
**Grape Flavored**  
**HIVES Relief**  
**24 hour Relief of ITCHING**  
**Due to Hives**  
**8 fl. oz. (240 mL)**

Dosing cup should be washed and left to air dry after each use. Do not use if seal on bottle is broken or missing.

**Manufactured by:**  
 Bajaj Medical, LLC  
 Chicago IL 60609, USA  
**Issued: 08/2025**



Base label without leaflet



Base label with leaflet

**Drug Facts** (continued)

**Warnings**  
 Severe Allergy Warning: Get emergency help immediately if you have hives along with any of the following symptoms:

- trouble swallowing
- swelling of tongue
- trouble speaking
- wheezing or problems breathing
- dizziness or loss of consciousness
- swelling in or around mouth
- drooling

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.

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**Drug Facts** (continued)

**Do not use**

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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.

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- liver or kidney disease. Your doctor should determine if you need a different dose
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**Drug Facts** (continued)

**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 toll-free number 1-800-222-1222.

**Drug Facts** (continued)

**Directions** • use with a 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
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**Other information**  
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**Drug Facts** (continued)

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

**Questions or comments?**  
 call toll-free 1-800-561-2528 weekdays

Manufactured by:  
 Bajaj Medical, LLC  
 Chicago IL 60609, USA  
 Issued: 08/2025



**PRINCIPAL DISPLAY PANEL:**  
**5 mL - NDC 61037-480-32**

**NDC 61037-480-32**

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

**6 yrs. & older**

**Antihistamine**  
 Grape Flavored

**HIVES Relief**

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

**100 Unit Dose Cups**

**(Each Cup Delivers 5 mL)**

Do not use if seal on cup is broken or missing.

**Manufactured by:**

Bajaj Medical, LLC  
Chicago IL 60609, USA

**Issued: 06/2025**

Base label without leaflet

Base label with leaflet

Leaflet Panel #1

Leaflet Panel #2

# CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride solution

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61037-480
<b>Route of Administration</b>	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		
SUCROSE (UNII: C151H8M554)				
SODIUM ACETATE (UNII: 4550K0SC9B)				
WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6A3C0OX)				
ACETIC ACID (UNII: Q40Q9N063P)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
Product Characteristics				
Color		Score		
Shape		Size		
Flavor	GRAPE	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61037-480-22	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/08/2025	
2	NDC:61037-480-23	480 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/08/2025	
3	NDC:61037-480-24	240 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/08/2025	
4	NDC:61037-480-26	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product	05/08/2025	
5	NDC:61037-480-32	5 mL in 1 BOX, UNIT-DOSE; Type 0: Not a Combination Product	05/08/2025	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA091327	05/08/2025		

**Labeler** - BAJAJ MEDICAL, LLC (078774921)

**Registrant** - BAJAJ MEDICAL, LLC (078774921)

## Establishment

Name	Address	ID/FEI	Business Operations
BAJAJ MEDICAL, LLC		078774921	analysis(61037-480) , label(61037-480) , manufacture(61037-480) , pack(61037-480)

Revised: 8/2025

BAJAJ MEDICAL, LLC