

CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride solution
BAJAJ MEDICAL, LLC

ALLERGY

Children's Cetirizine Hydrochloride Oral Solution, USP

1 mg/mL

2 yrs. & older

Drug Facts

Active Ingredient (in each 5 mL teaspoonful)

Cetirizine hydrochloride, USP 5 mg

Purpose

Antihistamine

Uses

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itchy, watery eyes
- 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 toll-free number 1-800-222-1222.

Directions

- use with a 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 2 to under 6 years of age	½ teaspoonful (2.5 mL) once daily. If needed, dose can be increased to a maximum of 1 teaspoonful (5 mL) once daily or ½ 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) 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 61037-480-02

NDC 61037-480-02

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

2 yrs. & older

Antihistamine

Grape Flavored

ALLERGY

Indoor and Outdoor Allergies

24 Hour Relief of:

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose

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: 01/2025

<p>NDC 61037-480-02 2 yrs. & older Children's Cetirizine Hydrochloride 1 mg/mL Oral Solution, USP</p>	 <p>Dosing cup should be washed and left to air dry after each use. Do not use if seal on bottle is broken or missing.</p>								
<p>Antihistamine Grape Flavored ALLERGY Indoor and Outdoor Allergies 24 Hour Relief of: • Sneezing • Runny Nose • Itchy, Watery Eyes • Itchy Throat or Nose 4 fl. oz. (120 mL)</p> <p>Manufactured by: Bajaj Medical, LLC Chicago IL 60609, USA Issued: 01/2025</p>	<table border="1"><tr><th colspan="2">Drug Facts</th></tr><tr><th>Active Ingredient (in each 5 mL teaspoonful)</th><th>Purpose</th></tr><tr><td>Cetirizine hydrochloride, USP 5 mg</td><td>Antihistamine</td></tr><tr><td colspan="2">Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: • runny nose • sneezing • itchy, watery eyes • itching of the nose or throat</td></tr></table> <p>Lift Here For Drug Facts ▲</p>	Drug Facts		Active Ingredient (in each 5 mL teaspoonful)	Purpose	Cetirizine hydrochloride, USP 5 mg	Antihistamine	Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: • runny nose • sneezing • itchy, watery eyes • itching of the nose or throat	
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Cetirizine hydrochloride, USP 5 mg	Antihistamine								
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Base label with leaflet

NDC 61037-480-02

2 yrs. & older

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



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

Antihistamine Grape Flavored

ALLERGY

Indoor and Outdoor Allergies

24 Hour Relief of:

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose

4 fl. oz. (120 mL)

Manufactured by:
Bajaj Medical, LLC
Chicago IL 60609, USA
Issued: 01/2025

Drug Facts

Active Ingredient (in each 5 mL teaspoonful)	Purpose
Cetirizine hydrochloride, USP 5 mg	Antihistamine

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: • runny nose • sneezing • itchy, watery eyes • itching of the nose or throat

Base label without leaflet

Drug Facts (continued)

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.

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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 doctor if an allergic reaction to this product occurs. Seek medical help right away.



Drug Facts (continued)

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 • 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.



Drug Facts (continued)

children 2 to under 6 years of age	½ teaspoonful (2.5 mL) once daily. If needed, dose can be increased to a maximum of 1 teaspoonful (5 mL) once daily or ½ 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) 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



Drug Facts (continued)

Questions or comments?

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

Manufactured by:
Bajaj Medical, LLC
Chicago IL 60609, USA

Issued: 01/2025

PRINCIPAL DISPLAY PANEL:

16 fl. oz. (480 mL) - NDC 61037-480-03

NDC 61037-480-03

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

2 yrs. & older

Antihistamine

Grape Flavored

ALLERGY

Indoor and Outdoor Allergies

24 Hour Relief of:

- *Sneezing*
- *Runny Nose*
- *Itchy, Watery Eyes*
- *Itchy Throat or Nose*

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: 01/2025

NDC 61037-480-03

2 yrs. & older

Children's

Cetirizine Hydrochloride

1 mg/mL Oral Solution, USP

Antihistamine

ALLERGY

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16 fl. oz. (480 mL)

Grape Flavored

Indoor and Outdoor Allergies

24 Hour Relief of:

- *Sneezing*
- *Runny Nose*
- *Itchy, Watery Eyes*
- *Itchy Throat or Nose*

Manufactured by:
Bajaj Medical, LLC
Chicago IL 60609, USA

Issued: 01/2025



Drug Facts

<i>Active Ingredient (in each 5 mL teaspoonful)</i>	<i>Purpose</i>
Cetirizine hydrochloride, USP 5 mg.....	Antihistamine

Uses

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat

Base label without leaflet

NDC 61037-480-03

2 yrs. & older

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Cetirizine Hydrochloride

1 mg/mL Oral Solution, USP

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ALLERGY

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16 fl. oz. (480 mL)

Grape Flavored

Indoor and Outdoor
Allergies

24 Hour Relief of:

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Manufactured by:
Bajaj Medical, LLC
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Lift Here For **Drug Facts** ▲

Base label with leaflet

Drug Facts (continued)**Warnings**

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- if breast-feeding: not recommended
- if pregnant: ask a health professional before use.

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Directions

- use with a dosing cup
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adults and children	1 teaspoonful (5 mL) or 2 teaspoonfuls (10 mL) once daily depending upon
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Drug Facts (continued)

6 years and over	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	½ teaspoonful (2.5 mL) once daily. If needed, dose can be increased to a maximum of 1 teaspoonful (5 mL) once daily or ½ 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
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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

Manufactured by: Bajaj Medical, LLC
Chicago IL 60609, USA
Issued: 01/2025

Leaflet Panel #1**PRINCIPAL DISPLAY PANEL:**

8 fl. oz. (240 mL) - NDC 61037-480-04

NDC 61037-480-04

Children's Cetirizine Hydrochloride Oral Solution, USP

1 mg/mL

2 yrs. & older

Antihistamine Grape Flavored

ALLERGY

Indoor and Outdoor Allergies

24 Hour Relief of:

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose

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

NDC 61037-480-04 2 yrs. & older

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

Antihistamine ALLERGY Grape Flavored
Indoor and Outdoor Allergies
24 Hour Relief of:
• Sneezing
• Runny Nose
• Itchy, Watery Eyes
• Itchy Throat or Nose

Drug Facts
Active Ingredient (in each 5 mL teaspoonful) Purpose
Cetrizine hydrochloride, USP 5 mg Antihistamine
Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: • runny nose • sneezing • itchy, watery eyes • itching of the nose or throat

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

3 61037 48004 4

Base label without leaflet

NDC 61037-480-04 2 yrs. & older

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

Antihistamine ALLERGY Grape Flavored
Indoor and Outdoor Allergies
24 Hour Relief of:
• Sneezing
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Manufactured by: Bajaj Medical, LLC Chicago IL 60609, USA Issued: 08/2025

3 61037 48004 4

Base label with leaflet

Drug Facts (continued)

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Drug Facts (continued)

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• if pregnant: ask a health professional before use.

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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.

Drug Facts (continued)

children 2 to under 6 years of age	½ teaspoonful (2.5 mL) once daily. If needed, dose can be increased to a maximum of 1 teaspoonful (5 mL) once daily or ½ 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
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Drug Facts (continued)

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

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

NDC 61037-480-04 2 yrs. & older

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

Antihistamine ALLERGY Grape Flavored
Indoor and Outdoor Allergies
24 Hour Relief of:
• Sneezing
• Runny Nose
• Itchy, Watery Eyes
• Itchy Throat or Nose

Drug Facts
Active Ingredient (in each 5 mL teaspoonful) Purpose
Cetrizine hydrochloride, USP 5 mg Antihistamine
Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: • runny nose • sneezing • itchy, watery eyes • itching of the nose or throat

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

3 61037 48004 4

PRINCIPAL DISPLAY PANEL:

5 mL - NDC 61037-480-12

NDC 61037-480-12

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

2 yrs. & older

Antihistamine

Grape Flavored

ALLERGY

Indoor and Outdoor Allergies

24 Hour Relief of:

- *Sneezing*
- *Runny Nose*
- *Itchy, Watery Eyes*
- *Itchy Throat or Nose*

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

NDC 61037-480-12

2 yrs. & older

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

**Antihistamine
ALLERGY**

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

**100 Unit Dose Cups
(Each Cup Delivers 5 mL)**

Grape Flavored

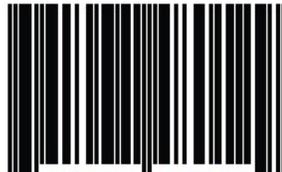
Indoor and Outdoor
Allergies

24 Hour Relief of:

- *Sneezing*
- *Runny Nose*
- *Itchy, Watery Eyes*
- *Itchy Throat or Nose*

Manufactured by:
Bajaj Medical, LLC
Chicago IL 60609, USA

Issued: 06/2025



3 61037 48012 9

Drug Facts

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

Uses

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat

Lift Here For **Drug Facts** ▲

Base label with leaflet

NDC 61037-480-12

2 yrs. & older

Children's

Cetirizine Hydrochloride

1 mg/mL Oral Solution, USP

Antihistamine

ALLERGY

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

**100 Unit Dose Cups
(Each Cup Delivers 5 mL)**

Grape Flavored

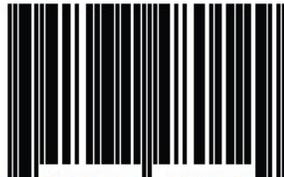
Indoor and Outdoor
Allergies

24 Hour Relief of:

- Sneezing
- Runny Nose
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- Itchy Throat or Nose

Manufactured by:
Bajaj Medical, LLC
Chicago IL 60609, USA

Issued: 06/2025



Drug Facts

<i>Active Ingredient (in each 5 mL teaspoonful)</i>	<i>Purpose</i>
Cetirizine hydrochloride, USP 5 mg.....	Antihistamine

Uses

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

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- sneezing
- itchy, watery eyes
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Base label without leaflet

Drug Facts (continued)

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Directions

- use with a dosing cup
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- mL = milliliter

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Drug Facts (continued)

6 years and over	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	½ teaspoonful (2.5 mL) once daily. If needed, dose can be increased to a maximum of 1 teaspoonful (5 mL) once daily or ½ teaspoonful (2.5 mL) every 12 hours. Do not give more than 1 teaspoonful (5 mL) in 24 hours.
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Manufactured by: Bajaj Medical, LLC
Chicago IL 60609, USA
Issued: 06/2025

Leaflet Panel #1

CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61037-480
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
SUCROSE (UNII: C151H8M554)	
SODIUM ACETATE (UNII: 4550K05C9B)	
WATER (UNII: 059QF0K00R)	
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:61037-480-02	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/08/2025	
2	NDC:61037-480-03	480 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/08/2025	
3	NDC:61037-480-04	240 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/08/2025	
4	NDC:61037-480-06	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product	05/08/2025	
5	NDC:61037-480-12	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