CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride solution BAIAI MEDICAL, LLC

ALLERGY

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

children 6	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.
N/Darc and	1 teaspoonful (5 mL) once daily; do not take more than 1 teaspoonful (5 mL) in 24 hours.
under 6	$\frac{1}{2}$ teaspoonful (2.5 mL) once daily. If needed, dose can be increased to a maximum of 1 teaspoonful (5 mL) once daily or $\frac{1}{2}$ 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



Base label with leaflet

NDC 61037-480-02 2 yrs. & older Children's **Cetirizine Hydrochloride** 1 mg/mL Oral Solution, USP

Antihistamine

Indoor and Outdoor Allergies

24 Hour Relief of:

ALLERGY

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

4 fl. oz. (120 mL)

Grape Flavored

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

Issued: 01/2025



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

Purpose

Drug Facts

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

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.

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 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 			
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 date 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

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

2 yrs. & older

Antihistamine

ALLERGY

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

16 fl. oz. (480 mL)

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

Issued: 01/2025



Indoor and Outdoor **Allergies**

24 Hour Relief of:

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

Drug Facts

Grape Flavored

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

Purpose

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

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

Base label without leaflet

NDC 61037-480-03 Children's **Cetirizine Hydrochloride**

1 mg/mL Oral Solution, USP

2 yrs. & older

Antihistamine

ALLERGY

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

16 fl. oz. (480 mL)

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

Issued: 01/2025



Indoor and Outdoor **Allergies**

24 Hour Relief of:

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

Drug Facts

Grape Flavored

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

Purpose

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

- runny nose
- sneezing
- · itchy, watery eyes

Lift Here For Drug Facts

Base label with leaflet

· 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 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

children

adults and 1 teaspoonful (5 mL) or 2 teaspoonfuls (10 mL) once daily depending upon

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		
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

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 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

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: 06/2025



Base label with leaflet

NDC 61037-480-04 2 yrs. & older Children's Cetirizine Hydrochloride 1 mg/mL Oral Solution, USP

Antihistamine ALLERGY

Indoor and Outdoor Allergies

24 Hour Relief of:

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

8 fl. oz. (240 mL)

Grape Flavored



Dosing cup should be washed and left to air dry after each use. Do not use if seal on bottle is 4 broken or missing.

Purpose

Drug Facts

Active Ingredient
(in each 5 mL teaspoonful)
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

Manufactured by:

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

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.

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
- \bullet 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.

• mL = milliliter adults and children 6 years and over adults 65 years and over • use with a dosing cup • find right dose on chart below • mL = milliliter 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. 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: 06/2025

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:

Baiai Medical, LLC Chicago IL 60609, USA

Issued: 06/2025

NDC 61037-480-12

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

2 yrs. & older

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



Drug Facts

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

Purpose

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

- runny nose
- sneezing
- · itchy, watery eyes

Lift Here For Drug Facts

· itching of the nose or throat

NDC 61037-480-12 Children's **Cetirizine Hydrochloride** 1 mg/mL Oral Solution, USP

2 yrs. & older

Antihistamine

ALLERGY

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

100 Unit Dose Cups (Each Cup Delivers 5 mL)

Grape Flavored

· itching of the nose or throat

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



Drug Facts

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

Purpose

Uses

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

- runny nose
- sneezing
- · itchy, watery eyes

Base label without leaflet

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 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

1 teaspoonful (5 mL) or 2 teaspoonfuls (10 mL) once daily depending upon

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		
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

Manufactured by: Bajaj Medical, LLC

Chicago IL 60609, USA Issued: 06/2025

Leaflet Panel #1

CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride solution

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: 640047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZ INE 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- 480-02	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)

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

Revised: 6/2025 BAJAJ MEDICAL, LLC