

CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride solution
Rising Pharma Holdings, Inc.

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 **1-844-474-7464**

PRINCIPAL DISPLAY PANEL:

4 fl. oz. (120 mL) - NDC 57237-357-12

NDC 57237-357-12

Children's Cetirizine Hydrochloride Oral Solution, USP

2 yrs. & older

1 mg/mL

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.

Distributed by:

Rising Pharma Holdings, Inc.

East Brunswick, NJ 08816

Issued: 09/2025



NDC 57237-357-12
2 yrs. & older

**Children's
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1 mg/mL


Antihistamine Grape Flavored
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Issued: 09/2025

4 fl. oz. (120 mL)



3 57237 35712 5


Drug Facts

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

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2.0000"

Lift Here For **Drug Facts**

Drug Facts (continued)

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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

- mL = milliliter
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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	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 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
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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

Drug Facts (continued)

Questions or comments?
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NDC 57237-357-12
2 yrs. & older

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

1 mg/mL


Antihistamine Grape Flavored
ALLERGY Indoor and Outdoor Allergies

24 Hour Relief of:

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

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4 fl. oz. (120 mL)



3 57237 35712 5

Drug Facts

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Lift Here For **Drug Facts**

8 fl. oz. (240 mL) - NDC 57237-357-24

NDC 57237-357-24

Children's 2 yrs. & older
Cetirizine Hydrochloride Oral Solution, USP

1 mg/mL

Antihistamine

Grape Flavored

ALLERGY

Indoor and Outdoor Allergies

24 Hour Relief of:

- Sneezing
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Drug Facts (continued)

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<p>Drug Facts (continued)</p> <p>If pregnant or breast-feeding: • if breast-feeding: not recommended • if pregnant: ask a health professional before use.</p> <p>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.</p>					
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Drug Facts (continued)	
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Drug Facts (continued)

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Rising Pharma Holdings, Inc.
East Brunswick, NJ 08816
Issued: 09/2025

 **Rising**
Pharmaceuticals

NDC 57237-357-2
2 yrs. & older

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

1 mg/mL

Antihistamine
ALLERGY

24 Hour Relief of:

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

Grape Flavored
Indoor and Outdoor Allergies

Distributed by:
Rising Pharma Holdings, Inc.
East Brunswick, NJ 08816
Issued: 09/20/25

8 fl. oz. (240 mL)

CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57237-357
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: 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:57237-357-12	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/11/2025	
2	NDC:57237-357-24	240 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/11/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091327	11/11/2025	

Labeler - Rising Pharma Holdings, Inc. (116880195)

Registrant - BAJAJ MEDICAL, LLC (078774921)

Establishment

Name	Address	ID/FEI	Business Operations
BAJAJ MEDICAL, LLC		078774921	analysis(57237-357) , label(57237-357) , manufacture(57237-357) , pack(57237-357)

Revised: 10/2025

Rising Pharma Holdings, Inc.