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

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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

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 **1-844-474-7464** 

PRINCIPAL DISPLAY PANEL: 4 fl. oz. (120 mL) - NDC 57237-357-12 NDC 57237-357-12

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

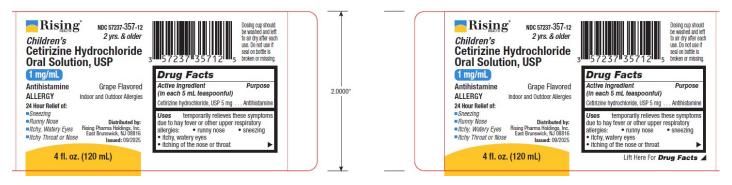
## 4 fl. oz. (120 mL)

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

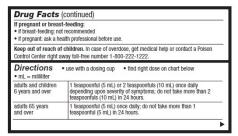
## Distributed by:

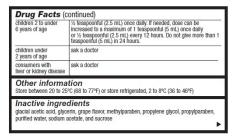
Rising Pharma Holdings, Inc. East Brunswick, NJ 08816

Issued: 09/2025

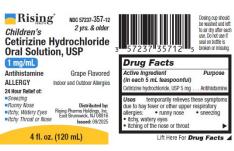












# PRINCIPAL DISPLAY PANEL: 8 fl. oz. (240 mL) - NDC 57237-357-24

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
- Runny Nose
- Itchy, Watery Eyes
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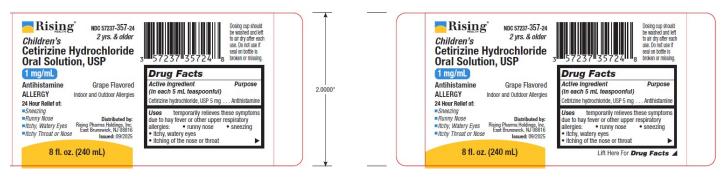
## 8 fl. oz. (240 mL)

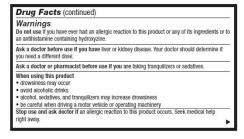
Dosing cup should be washed and left to air dry after each use. Do not use if seal on bottle is broken or missing.

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(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.			
• 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.			
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	1/3 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 informa	tion °C (68 to 77°F) or store refrigerated, 2 to 8°C (36 to 46°F)	
Store between 20 to 25	the second secon	

Rising\* NDC 57237-357-24
2 yrs. & older
Cetirizine Hydrochloride
Oral Solution, USP

1 mg/mL
Anthistamine Grape Flavored
ALLERGY Indoor and Outdoor Allergies
24 Hour Relief of:
Senezing
Runny Mose
Hichy Marey Fyss
Hichy Throat or Nose
Senezing
Flamme Hoddings, Inc.
East Brunweisk, IN 108816
Estance 1082/025

8 fl. oz. (240 mL)



Lift Here For Drug Facts

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

### **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

CETIRIZINE HYDROCHLORIDE (UNII: 640047KTOA) (CETIRIZINE UNII:Y07261ME24)

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: A218C7H19T)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
PROPYLPARABEN (UNII: Z8IX2SC10H)				

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

P	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.