

**CETIRIZINE HYDROCHLORIDE- cetirizine solution**  
**Amneal Pharmaceuticals LLC**

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**Cetirizine Hydrochloride Oral Solution**  
**Antihistamine/ Allergy**  
**1 mg/mL**

\*Compared to Children's Zyrtec<sup>®</sup> active ingredient

**Drug Facts**

**ACTIVE INGREDIENT**

**(in each 5 mL teaspoonful)**

Cetirizine HCl 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 and 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 breastfeeding:**

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

**KEEP OUT OF REACH OF CHILDREN**

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

**Directions**

- use only with enclosed 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)
- **TAMPER EVIDENT: DO NOT USE IF NECKBAND IMPRINTED “SEALED FOR YOUR PROTECTION” IS BROKEN OR MISSING.**

**INACTIVE INGREDIENTS**

Sucrose, Glycerin, Propylene Glycol, Methylparaben, Propylparaben, Sodium Acetate, Glacial Acetic Acid, Artificial Grape Flavor, Purified Water.

**Questions?**

Call 1-877-835-5472

Monday through Friday 9AM – 5PM EST.

\*This product is not manufactured or distributed by McNeil-PPC, Inc., distributor of Zyrtec® . Zyrtec® is a registered trademark of UCB Pharma, S.A.

Distributed by: **Amneal Pharmaceuticals**  
Glasgow, KY 42141

Rev. 03-2015-01

## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

\*Compare to Children's Zyrtec®  
active ingredient

NDC 65162-005-86

# CETIRIZINE HCl ORAL SOLUTION

**Antihistamine/Allergy**

## 1 mg/mL

**ALLERGY**  
Indoor & Outdoor Allergies

**24 Hour Relief of:**

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

**4 FL OZ (118mL)**

**2 Years & Older**

**Grape**  
Flavored Syrup



**amneal**  
PHARMACEUTICALS

**Active ingredient (in each 5 mL teaspoonful)**  
Cetirizine HCl 5mg

**Purpose**  
Antihistamine

**Uses** temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ runny nose ■ itchy, watery eyes ■ sneezing ■ itching of the nose and 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. (1-800-222-1222)

**Directions** ■ use only with enclosed dosing cup ■ mL = milliliter ■ adults and children 6 years and over: 1 teaspoonful (5 mL) or 2 teaspoonfuls (10mL) 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: 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 ■ consumers with liver or kidney disease: ask a doctor

**Other information** ■ store between 20° to 25°C (68° to 77°F)

**■ TAMPER EVIDENT: DO NOT USE IF NECKBAND IMPRINTED "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING.**

**Inactive ingredients** Sucrose, Glycerin, Propylene Glycol, Methylparaben, Propylparaben, Sodium Acetate, Glacial Acetate Acid, Artificial Grape Flavor, Purified Water.

**Questions?** Call 1-877-835-5472, Monday through Friday 9AM - 5PM EST.

**Dosing cup should be washed and left to air dry after each use.**

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Rev. 03-2015-01

Lot No:  
Exp. Date:

N 3 65162-005-86 8



# CETIRIZINE HCl ORAL SOLUTION

Antihistamine/Allergy

1 mg/mL

For Children 2 Years & Older

**ALLERGY**



\*Compare to Children's Zyrtec®  
active ingredient

NDC 65162-005-86

# CETIRIZINE HCl ORAL SOLUTION

Antihistamine/Allergy

1 mg/mL

**ALLERGY**

Indoor & Outdoor Allergies

24 Hour Relief of:

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

2 Years & Older

**Grape**  
Flavored Syrup



**DOSING CUP INCLUDED**  
Dosing cup should be washed and  
left to air dry after each use.



\*Compare to Children's Zyrtec®  
active ingredient

NDC 65162-005-86

# CETIRIZINE HCl ORAL SOLUTION

Antihistamine/Allergy

1 mg/mL

**ALLERGY**

Indoor & Outdoor Allergies

24 Hour Relief of:

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

2 Years & Older

**Grape**  
Flavored Syrup



**4 FL OZ (118mL)**

Do not use if imprinted foil inner seal on bottle is broken or missing.



RETAIN CARTON FOR COMPLETE PRODUCT  
INFORMATION.

## Drug Facts

**Active ingredient** Purpose  
(in each 5 mL teaspoonful)  
Cetirizine HCl 5mg.....Antihistamine

## Uses

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:  
 ■ runny nose ■ itchy, watery eyes  
 ■ sneezing ■ itching of the nose and 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. (1-800-222-1222)

## Drug Facts (continued)

**Directions** ■ use only with enclosed 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 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

consumers with liver or kidney disease ask a doctor

## Other information

- store between 20° to 25°C (68° to 77°F)
- **TAMPER EVIDENT; DO NOT USE IF NECKBAND IMPRINTED "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING.**
- See end panel for lot number and expiration date.

**Inactive ingredients** Sucrose, Glycerin, Propylene Glycol, Methylparaben, Propylparaben, Sodium Acetate, Glacial Acetic Acid, Artificial Grape Flavor, Purified Water.

**Questions?** Call 1-877-835-5472  
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Glasgow, KY 42141

Rev. 03-2015-01

# CETIRIZINE HYDROCHLORIDE

cetirizine solution

## Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:65162-005

**Route of Administration**

ORAL



N 3 65162-005-86 8

Lot No.:

Exp. Date:

<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>			<b>Basis of Strength</b>	<b>Strength</b>
CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)			CETIRIZINE HYDROCHLORIDE	5 mg in 5 mL
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
ACETIC ACID (UNII: Q40Q9N063P)				
GLYCERIN (UNII: PDC6A3C0OX)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
SODIUM ACETATE (UNII: 4550K0SC9B)				
SUCROSE (UNII: C151H8M554)				
WATER (UNII: 059QF0KO0R)				
<b>Product Characteristics</b>				
<b>Color</b>	yellow (CLEAR TO PALE YELLOW)		<b>Score</b>	
<b>Shape</b>			<b>Size</b>	
<b>Flavor</b>	GRAPE		<b>Imprint Code</b>	
<b>Contains</b>				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65162-005-86	1 in 1 CARTON	10/07/2009	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA090765	10/07/2009		

**Labeler** - Amneal Pharmaceuticals LLC (123797875)

Revised: 10/2024

Amneal Pharmaceuticals LLC