

CETIRIZINE HYDROCHLORIDE- cetirizine solution
Amneal Pharmaceuticals LLC

Cetirizine Hydrochloride Oral Solution
Antihistamine/ Allergy
1 mg/mL

*Compared to Children's Zyrtec® 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, Glucal 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:



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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:

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
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)	

Product Characteristics

Color	yellow (CLEAR TO PALE YELLOW)	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	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		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090765	10/07/2009	

Labeler - Amneal Pharmaceuticals LLC (123797875)

Revised: 12/2023

Amneal Pharmaceuticals LLC