CETIRIZINE HYDROCHLORIDE- cetirizine solution
Amneal Pharmaceuticals LLC

Cetirizine Hydrochloride Oral Solution
Antihistamine/ Hives Relief
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

relieves itching due to hives (urticaria). This product will not prevent hives or a allergic skin reaction from occurring.

WARNINGS

Severe Allergy Warning: Get emergency help **immediately** if you have hives along with any of the following symptoms:

- trouble swallowing
- swelling of tongue
- trouble speaking
- wheezing or problems breathing
- dizziness or loss of consciousness
- swelling in or around the mouth
- drooling

The symptoms may be signs of anaphylactic shock. This condition can be life threatening if not treated by a health professional **immediately**. Symptoms of anaphylactic shock may occur when hives first appear or up to a few hours later.

Not a substitute for Epinephrine. If your doctor has prescribed an epinephrine injection for "anaphylaxis" or severe allergy symptoms that could occur with your hives, never use this product as a substitute for the epinephrine injector. If you have been prescribed an epinephrine injector, you should carry it with you at all times.

Do not use

- to **prevent** hives from any known cause such as:
  - foods
  - insect stings
  - medicines
  - latex or rubber gloves

because this product will not stop hives from occurring. Avoiding the cause of your hives is the only way to prevent them. Hives can sometimes be serious. If you do not know the cause of your hives, see your doctor for a medical exam. Your doctor may be able to help you find a cause

- 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.
- hives that are an unusual color, look bruised or blistered
- hives that do not itch

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.
- symptoms do not improve after 3 days of treatment
- the hives have lasted more than 6 weeks

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 of 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	1 teaspoonful (5 mL) or 2 teaspoonfuls (10 mL) once daily depending upon severity of symptoms;

and over	do not take more than 2 teaspoonfuls (10 mL) in 24 hours.
adults 56 years and over	1 teaspoonful (5 mL) once daily; do not take more than 1 teaspoonful (5 mL) in 24 hours.
children under 6 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 MISSSING.**

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

NDC 65162-003-86

*Compare to Children's Zyrtec® active ingredient

CETIRIZINE HCl ORAL SOLUTION

Antihistamine/Hives Relief

1 mg/mL

24 Hour Relief of ITCHING due to Hives

Grape Flavored Syrup

6 Years & Older

4 FL OZ (118mL)

amneal PHARMACEUTICALS

Active Ingredient (in each 5 mL teaspoonful) ***Purpose***

Cetirizine HCl 5mg.....Antihistamine

Uses relieves itching due to hives (urticaria). This product will not prevent hives or an allergic skin reaction from occurring. ***Warnings*** **Severe Allergy Warning:** Get emergency help **immediately** if you have hives along with any of the following symptoms: ■ trouble swallowing ■ dizziness or loss of consciousness ■ swelling of tongue ■ swelling in or around mouth ■ trouble speaking ■ drooling ■ wheezing or problems breathing. These symptoms may be signs of anaphylactic shock. This condition can be life threatening if not treated by a health professional **immediately**. Symptoms of anaphylactic shock may occur when hives first appear or up to a few hours later. **Not a Substitute for Epinephrine.** If your doctor has prescribed an epinephrine injector for "anaphylaxis" or severe allergy symptoms that could occur with your hives, never use this product as a substitute for the epinephrine injector. If you have been prescribed an epinephrine injector, you should carry it with you at all times. **Do not use** ■ to **prevent** hives from any known cause such as: ■ foods ■ insect stings ■ medicines ■ latex or rubber gloves because this product will not stop hives from occurring. Avoiding the cause of your hives is the only way to prevent them. Hives can sometimes be serious. If you do not know the cause of your hives, see your doctor for a medical exam. Your doctor may be able to help you find a cause. ■ 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. ■ hives that are an unusual color, look bruised or blistered ■ hives that do not itch **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. ■ symptoms do not improve after 3 days of treatment ■ the hives have lasted more than 6 weeks **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 under 6 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.

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

Distributed by: **Amneal Pharmaceuticals,** Glasgow, KY 42141 Rev. 03-2015-01

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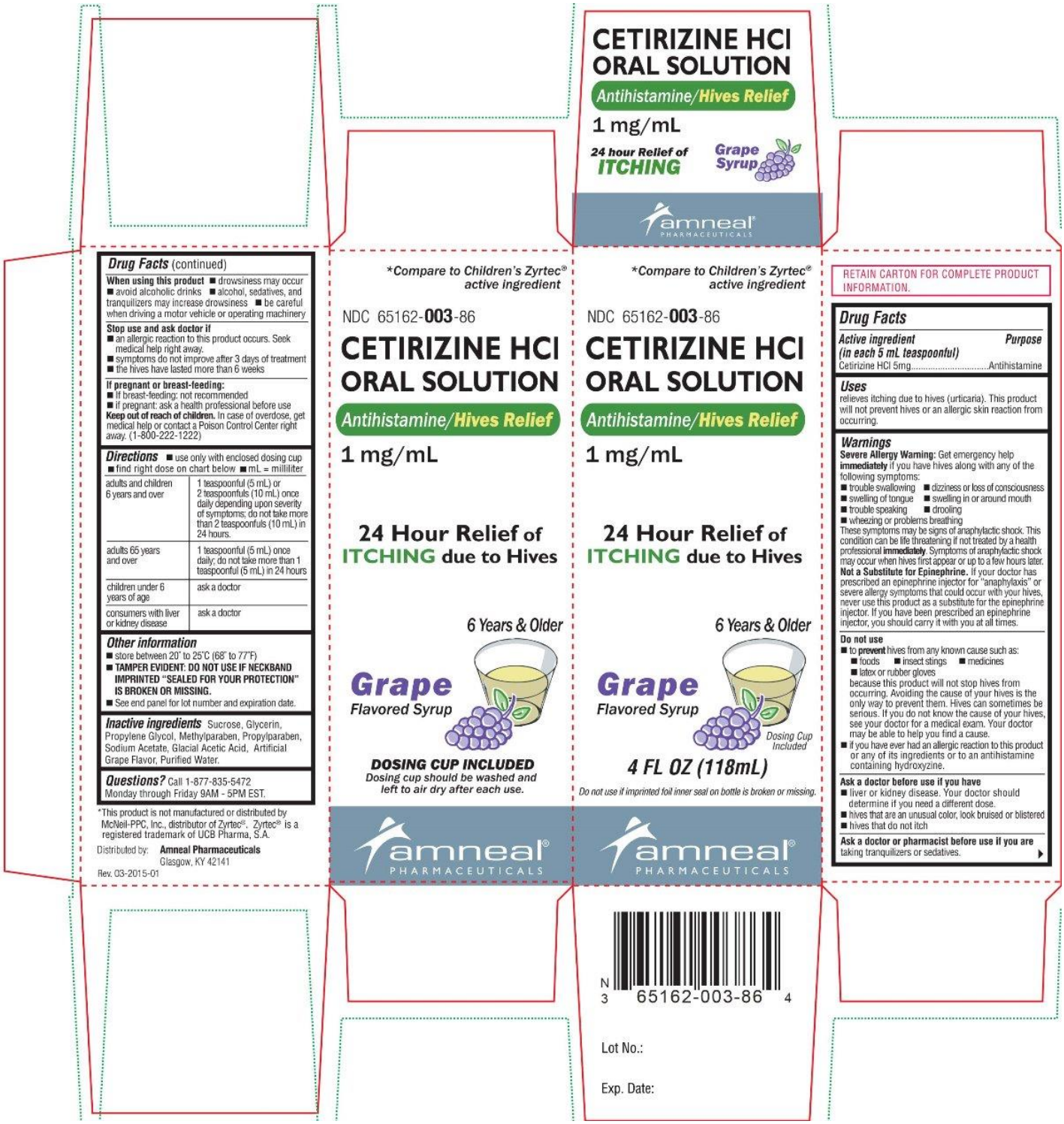
N 3 65162-003-86 4

Lot No:
Exp. Date:



CETIRIZINE HYDROCHLORIDE

cetirizine solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:65162-003
Route of Administration	ORAL		

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:65162-003-86	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