

**CETIRIZINE HYDROCHLORIDE HIVES RELIEF- cetirizine tablet**  
**Amneal Pharmaceuticals LLC**

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**CETIRIZINE HYDROCHLORIDE TABLETS**

***Drug Facts***

**ACTIVE INGREDIENT**

***(in each tablet)***

Cetirizine HCl, USP 5 mg

**PURPOSE**

Antihistamine

**INDICATIONS AND USAGE**

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**

### **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 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 its ingredients or to an antihistamine containing hydroxyzine.

## **ASK DOCTOR**

### **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 DOCTOR/PHARMACIST**

**Ask a doctor of pharmacist before use if you are** taking tranquilizers or sedatives.

## **WHEN USING**

### **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**

### **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

## **PREGNANCY OR BREAST FEEDING**

**If pregnant or breast-feeding:**

- 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**

Adults and children 6 years and over	1 tablet (5 mg) or 2 tablets (10 mg) once daily depending upon severity of symptoms; do not take more than 2 tablets (10 mg) in 24 hours.
Adults 65 years and over	1 tablet (5 mg) once daily; do not take more than 1 tablet (5 mg) in 24 hours.
Children under 6 years of age	ask a doctor
Consumers with liver or kidney disease	ask a doctor

**OTHER INFORMATION*****Other information***

- store between 20° to 25°C (68° to 77°F)

**INACTIVE INGREDIENTS*****Inactive Ingredients***

lactose monohydrate, magnesium stearate, polyvinyl alcohol, polyethylene glycol, povidone, starch, talc and titanium dioxide.

**OTC - QUESTIONS*****Questions or Comments?***

**Call 1-877-835-5472**

**Monday through Friday 9AM - 5PM EST.**

Distributed by:

**Amneal Pharmaceuticals LLC**  
Bridgewater, NJ 08807

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 65162-145-03

# Cetirizine Hydrochloride Tablets, USP

**5 mg**

Antihistamine  
**HIVES RELIEF**

30 Tablets



**Drug Facts**

**Active ingredient (in each tablet)** Purpose  
Cetirizine HCl, USP 5 mg.....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

**Do not use if imprinted foil inner seal on bottle is broken or missing.**  
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 Bridgewater, NJ 08807  
 Rev. 08-2023-01



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Lot No: \_\_\_\_\_  
Exp. Date: \_\_\_\_\_

Non-Varnish Area

PEEL BACK FOR ADDITIONAL DRUG FACTS

**Drug Facts (continued)**

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.

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**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 medical exam. Your doctor may be able to help you find a cause.
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- liver or kidney disease. Your doctor should determine if you need a different dose.
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**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

**Drug Facts (continued)**

**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 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)

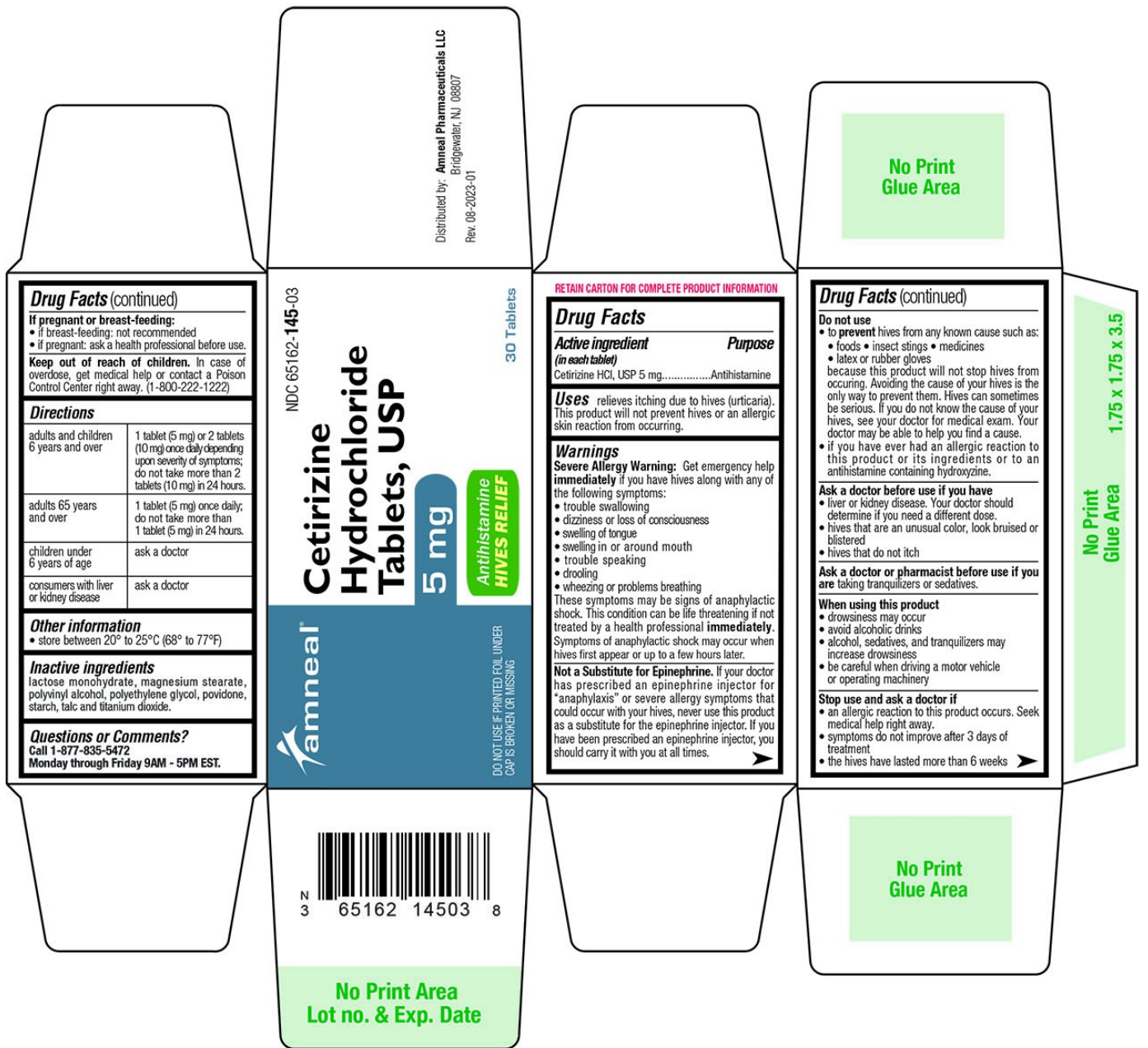
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**Other information**

- store between 20° to 25°C (68° to 77°F)

**Inactive ingredients**  
 lactose monohydrate, magnesium stearate, polyvinyl alcohol, polyethylene glycol, povidone, starch, talc and titanium dioxide.

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



## CETIRIZINE HYDROCHLORIDE HIVES RELIEF

cetirizine tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:65162-145
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

Color	white	Score	no score
Shape	OVAL	Size	6mm
Flavor		Imprint Code	IP;45
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65162-145-03	1 in 1 CARTON	01/21/2010	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:65162-145-50	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/21/2010	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078780	01/21/2010	

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

## Establishment

Name	Address	ID/FEI	Business Operations
Amneal Pharmaceuticals of New York, LLC		831227801	analysis(65162-145) , label(65162-145) , manufacture(65162-145) , pack(65162-145)

Revised: 8/2023

Amneal Pharmaceuticals LLC