CETIRIZINE HYDROCHLORIDE HIVES RELIEF- cetirizine tablet
Amneal Pharmaceuticals

CETIRIZINE HYDROCHLORIDE TABLETS

Drug Facts

ACTIVE INGREDIENT

(in each tablet)

Cetirizine HCl 10 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.

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

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

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.

DOSAGE AND ADMINISTRATION

Adults andchildrenOne 10 mg tablet once daily; do not take more than one 10 mg tablet in

6years andover	24 hours. A 5 mg product may be appropriate for less sever symptoms
Adults 65years andover	Ask a doctor
Childrenunder 6 yearsof age	ask a doctor
Consumerswith liver orkidney disease	ask a doctor

OTHER INFORMATION

Other information

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

INACTIVE INGREDIENT

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**

Glasgow, KY 42141

Rev. 01-2009

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

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.

Directions

adults and children 6 years and over	one 10 mg tablet once daily; do not take more than one 10 mg tablet in 24 hours. A 5 mg product may be appropriate for less severe symptoms.
adults 65 years and over	ask a doctor
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)

Inactive ingredients

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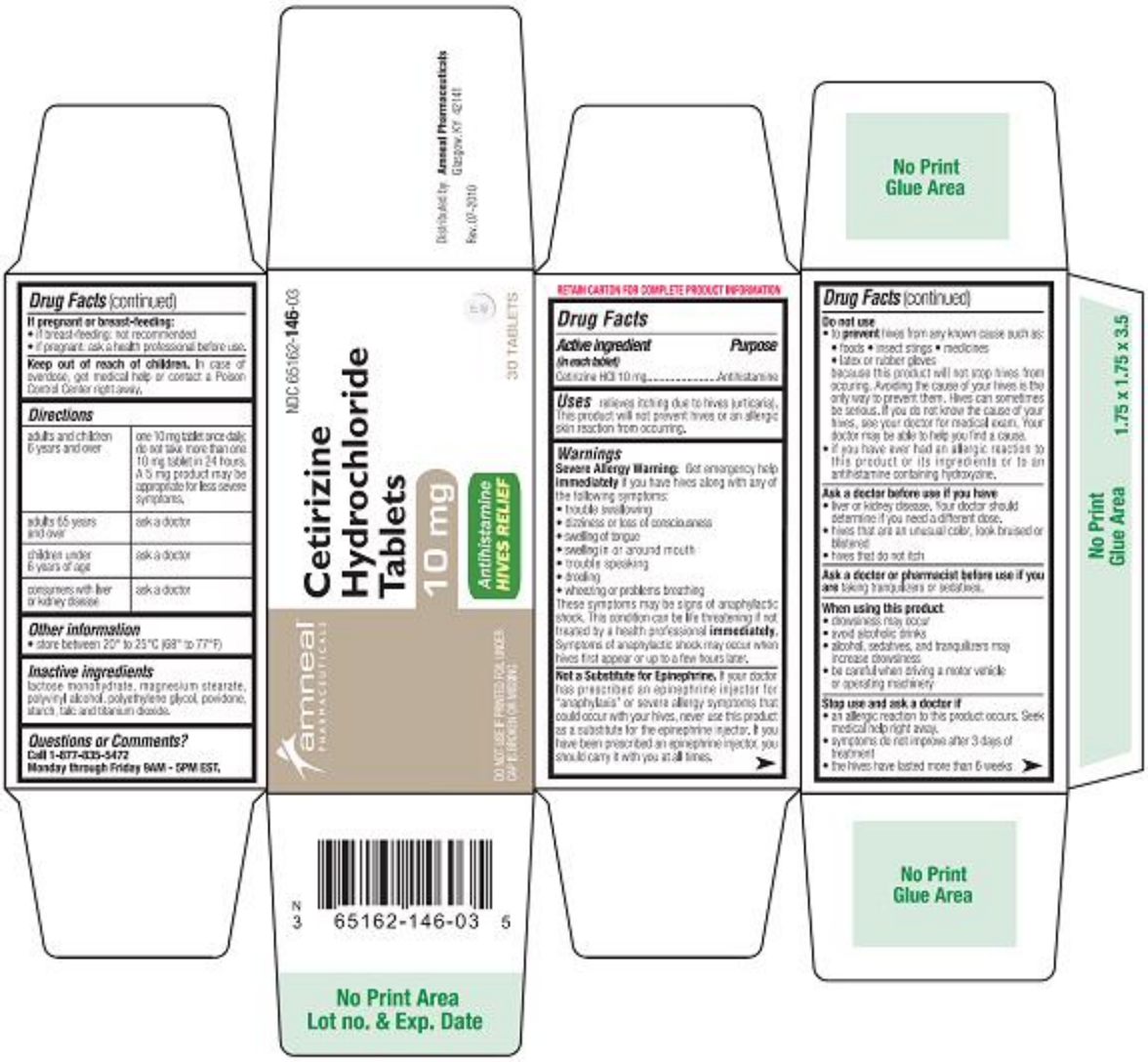
• hives that are an unusual color, look bruised or blistered • hives that do not itch

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



CETIRIZINE HYDROCHLORIDE HIVES RELIEF

cetirizine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:65162-146
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	10 mg

Inactive Ingredients	
Ingredient Name	**Strength**
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	

POLYETHYLENE GLYCOL (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**	8mm
Flavor		**Imprint Code**	IP;46
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65162-146-03	1 in 1 CARTON		
1		30 in 1 BOTTLE		
2	NDC:65162-146-50	500 in 1 BOTTLE		

Marketing Information

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

Labeler - Amneal Pharmaceuticals (123797875)

Registrant - Amneal Pharmaceuticals (123797875)

Establishment

Name	Address	ID/FEI	Business Operations
Amneal Pharmaceuticals		831227801	ANALYSIS, LABEL, MANUFACTURE, PACK

Revised: 2/2012 Amneal Pharmaceuticals