CETIRIZINE HYDROCHLORIDE - cetirizine tablet
Amneal Pharmaceuticals

CETIRIZINE HYDROCHLORIDE TABLETS

Drug Facts

ACTIVE INGREDIENT

(in each tablet)

Cetirizine HCl 10 mg

PURPOSE

Antihistamine

INDICATIONS AND USAGE

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat

DO NOT USE

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 DOCTOR

Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.

ASK DOCTOR/PHARMACIST

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

When using this product

- drowsiness may occur
- avoid alcoholic drink
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

WARNINGS

Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.

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 andchildren 6years andover	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 sever symptoms.
Adults 65years andover	Ask a doctor.
Childrenunder 6 yearsof age	ask a doctor
Consumerswith liver orkidneydisease	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

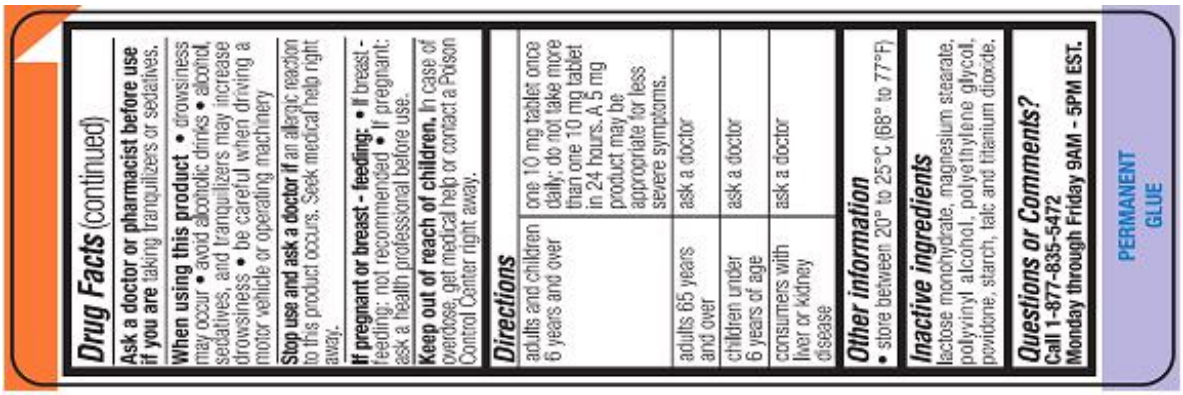
Monday through Friday 9AM-5PM EST

Distributed by: **Amneal Pharmaceuticals**

Glasgow, KY 42141

Rev. 01-2009

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



CETIRIZINE HYDROCHLORIDE

cetirizine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:65162-046
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:65162-046-03	1 in 1 CARTON		
1		30 in 1 BOTTLE		
2	NDC:65162-046-50	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