CETIRIZINE HYDROCHLORIDE- cetirizine tablet
Amneal Pharmaceuticals LLC

CETIRIZINE HYDROCHLORIDE TABLETS

Drug Facts

ACTIVE INGREDIENT

(in each tablet)

Cetirizine HCl, USP 5 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

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 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 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.

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 6years 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 65years 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?

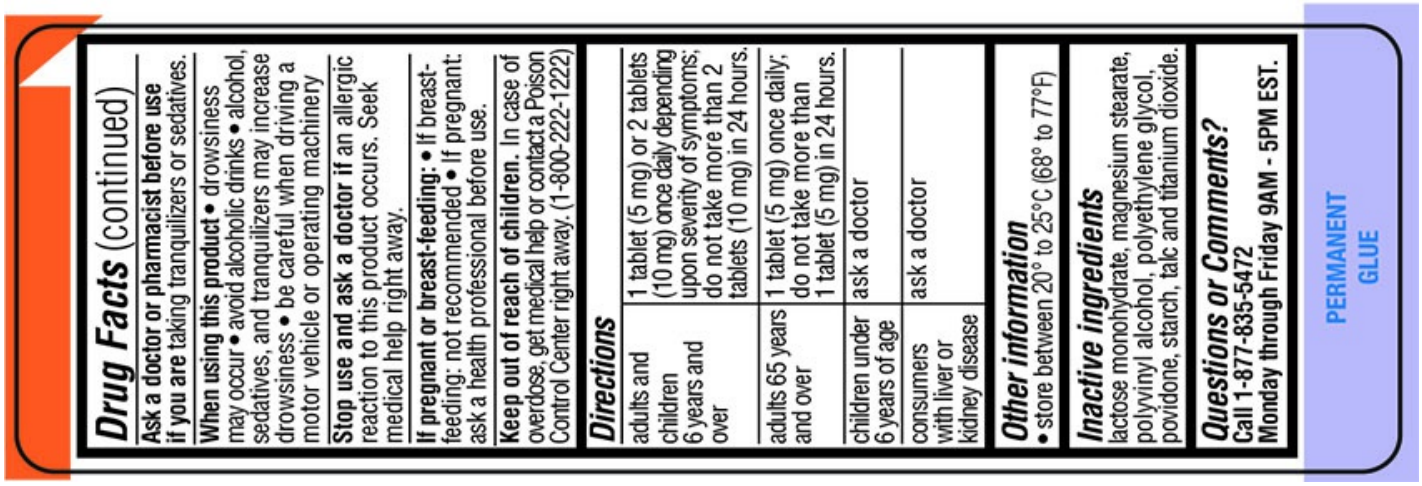
Call 1-877-835-5472

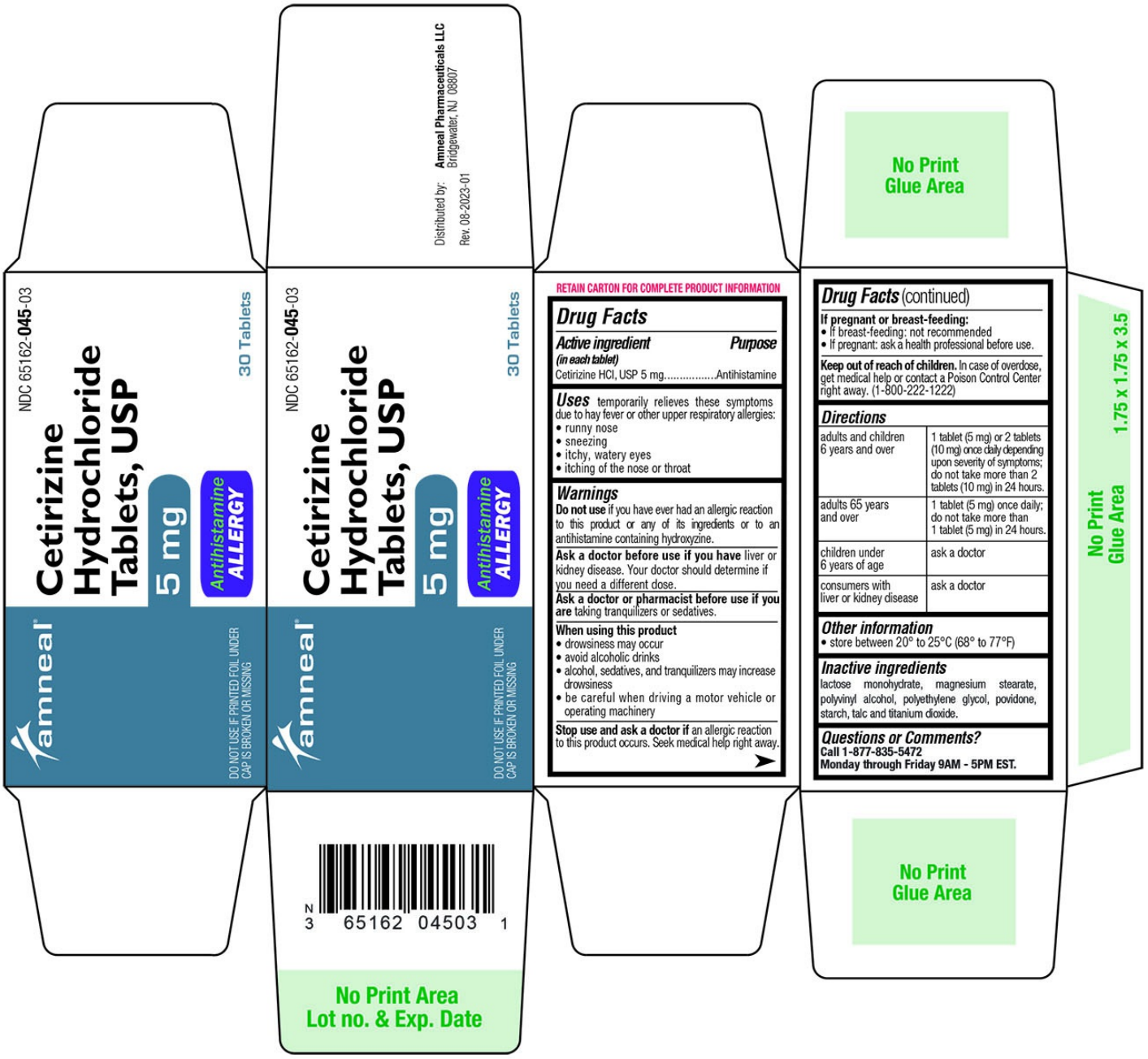
Monday through Friday 9AM - 5PM EST.

Distributed by:
Amneal Pharmaceuticals LLC
Bridgewater, NJ08807

Rev. 08-2023-01

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL





CETIRIZINE HYDROCHLORIDE

cetirizine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:65162-045
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

Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
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:65162-045-03	1 in 1 CARTON	01/21/2010	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:65162-045-50	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(65162-045) , label(65162-045) , manufacture(65162-045) , pack(65162-045)