

CETIRIZINE HYDROCHLORIDE- cetirizine tablet
Amneal Pharmaceuticals LLC

CETIRIZINE HYDROCHLORIDE TABLETS

Drug Facts

ACTIVE INGREDIENT

(in each tablet)

Cetirizine HCl, USP 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

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)

DOSAGE AND ADMINISTRATION

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 sever 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

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 LLC

Bridgewater, NJ 08807

Rev. 07-2024-01

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65162-046-03

Cetirizine Hydrochloride Tablets, USP

10 mg

Antihistamine ALLERGY

30 Tablets



Drug Facts
Active ingredient (in each tablet) Purpose Cetirizine HCl, USP 10 mg.....Antihistamine
Uses 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 a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.

Do not use if imprinted foil inner seal on bottle is broken or missing.

Distributed by: **Amneal Pharmaceuticals LLC**
Bridgewater, NJ 08807
Rev. 07-2024-01



N 3 65162 04603 8

Lot No: _____
Exp. Date: _____

Non-Varnish Area

PEEL BACK FOR ADDITIONAL DRUG FACTS

Drug Facts (continued)
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.
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
adults 65 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 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.

PERMANENT GLUE



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, 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	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	01/21/2010	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:65162-046-50	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(65162-046) , label(65162-046) , manufacture(65162-046) , pack(65162-046)

Revised: 7/2024

Amneal Pharmaceuticals LLC