ALL DAY ALLERGY ANTIHISTAMINE- cetirizine hcl tablet
P and L Development of New York Corporation

Cetirizine Hydrochloride Tablets

Active Ingredient (in each tablet)

Cetirizine HCl 10 mg

Purpose

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.

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.

Directions

Adults and children 6 years and over	Take 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

colloidal silicon dioxide, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, sodium starch glycolate, titanium dioxide.

Questions or comments?

Call toll free 1-877-753-3935 Monday-Friday 9am-5pm EST.

Principal Display Panel

†Compare to the active ingredient in Zyrtec®

24 Hour

All Day Allergy

Cetirizine HCl Tablets, 10 mg

Antihistamine

Allergy Relief of:

- Runny nose
- sneezing
- Itchy, watery eyes
- Itching of the nose or throat

Treats Indoor & Outdoor allergies

†This product is not manufactured or distributed by McNeil Consumer Healthcare Division of McNeil-PPC, Inc., owner of the registered trademark Zyrtec®

THIS PRODUCT IS PACKAGED IN A CHILD RESISTANT AND TAMPER EVIDENT

PACKAGE. USE ONLY IF BLISTERS ARE INTACT.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Distributed by:

PL Developments

Westbury, NY 11590

PRODUCT OF INDIA

Product Label

Drug Facts

Active ingredient (in each tablet)	Purpose
Cetirizine HCl 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.

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.

Directions

adults and children 6 years and over	Take 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 colloidal silicon dioxide, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, sodium starch glycolate, titanium dioxide.

Questions or comments? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

24 Hour All Day Allergy

†Compare to the active ingredient in **Zyrtec®**

NDC 59726-220-14

24 Hour All Day Allergy

Cetirizine HCl Tablets, 10 mg
Antihistamine

Allergy Relief of: runny nose, sneezing, itchy, watery eyes
itching of the nose or throat

14 TABLETS

Treats Indoor & Outdoor Allergies

THIS PRODUCT IS PACKAGED IN A CHILD RESISTANT AND TAMPER EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Lot No.:

Exp. Date:

†This product is not manufactured or distributed by McNeil Consumer Healthcare, Division of McNeil-PPC, Inc., owner of the registered trademark Zyrtec®.

PL Developments
200 Hicks Street
Westbury, NY 11590

Product of India

Cetirizine HCl 10 mg tablets

ALL DAY ALLERGY ANTIHISTAMINE

cetirizine hcl tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59726-220
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**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POVIDONES (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	WHITE	**Score**	no score
Shape	OVAL	**Size**	8mm
Flavor		**Imprint Code**	W989
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:59726-220-14	1 in 1 CARTON		
1		14 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078427	12/05/2012	

Labeler - P and L Development of New York Corporation (800014821)

Registrant - P and L Development of New York Corporation (800014821)

Revised: 12/2012 P and L Development of New York Corporation