CETIRIZINE HYDROCHLORIDE - cetirizine hydrochloride tablet
Unique Pharmaceutical Laboratories

Cetirizine Hydrochloride Tablets, 5 mg, Allergy

Active Ingredients

Active Ingredients (in each tablet)	**Purpose**
Cetirizine HCl 5 mg	Antihistimine

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

- drowsines may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinary.

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 Poison Control Center right away.

Directions

Adults and children 6 years and over	1 to 2 tablets once daily depending upon severity of symptoms; do not take more than 2 tablets in 24 hours.
Adults 65 years and over	1 tablet1 tablet once a day; do not take more than

Adults 65 years and over	1 tablet in 24 hours.
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

hypromellose, lactose, magnesium stearate, maize starch, polyethylene glycol, povidone, titanium dioxide.

Questions?

Call 1-866-562-4597

Manufactured for **Unique Pharmaceutical Laboratories** (A Div. of J. B. Chemicals & Pharmaceuticals Ltd.), Mumbai, INDIA.

Manufactured by **Unique Pharmaceutical Laboratories** (A Div. of J. B. Chemicals & Pharmaceuticals Ltd.), Mumbai, INDIA.

Cetirizine Hydrochloride Tablets 5 mg Container Label

NDC 16571-401-10

Original Prescription Strength

Cetirizine Hydrochloride

Tablets 5 mg

Antihistamine 24 Hour Relief of:

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose

100 Tablets

Allergy

Indoor & Outdoor

Allergies

PACK PHARMACEUTICALS LLC

CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67668-161
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**
hypromellose (UNII: 3NXW29V3WO)	
lactose (UNII: J2B2A4N98G)	
magnesium stearate (UNII: 70097M6I30)	
starch, corn (UNII: O8232NY3SJ)	
polyethylene glycol (UNII: 3WJQ0SDW1A)	
povidone (UNII: FZ989GH94E)	
titanium dioxide (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	white (White)	**Score**	no score
Shape	BULLET (Barrel Shaped)	**Size**	7mm
Flavor		**Imprint Code**	CTN;5
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:67668-161-30	30 in 1 BOTTLE		
2	NDC:67668-161-45	45 in 1 BOTTLE		
3	NDC:67668-161-00	100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077829	10/01/2009	

Labeler - Unique Pharmaceutical Laboratories (917165052)

Registrant - Unique Pharmaceutical Laboratories (917165052)

Establishment

Name	Address	ID/FEI	Business Operations
Unique Pharmaceutical Laboratories		650434645	MANUFACTURE, analysis

Revised: 12/2009