CETIRIZINE HYDROCHLORIDE - cetirizine hydrochloride tablet Unique Pharmaceutical Laboratories

Cetirizine Hydrochloride Tablets, 5 mg, Allergy

Active Ingredients

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.
A dulta GE Transa and array	1 tablet1 tablet once a day; do not take more than

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.

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Cetirizine Hydrochloride Tablets 5 mg Container Label

NDC 16571-401-10

Original Prescription Strength

Cetirizine Hydrochloride

Tablets 5 mg

Antihis tamine 24 Hour Relief of:

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

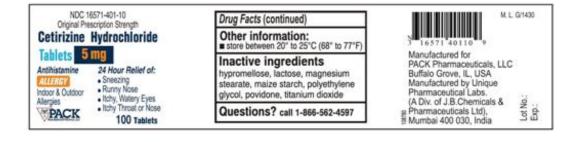
100 Tablets

Allergy

Indoor & Outdoor

Allergies

PACK PHARMACEUTICALS LLC



CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

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Product	Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:67668-161

Route of Administration ORAL

Active Ingredient/Active Moiety

ricave ingredient ricave matter				
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

2 7 0 4 4 0 0 7 2 4 2 0 0 0 7 2 0 0 0 0 0 0 0 0 0 0 0 0 0 0			
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

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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 Unique Pharmaceutical Laboratories