

**CETIRIZINE HYDROCHLORIDE - cetirizine hydrochloride tablet**  
**Unique Pharmaceutical Laboratories**

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**Cetirizine Hydrochloride Tablets, 10 mg, Allergy**

**Active Ingredients**

**Active Ingredients (in each tablet)**

Cetirizine HCl 10 mg.....Antihistimine

**Purpose**

**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 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 Poison Control Center right away.

**Directions**

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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

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### 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 10 mg Container Label

NDC 16571-402-10

Original Prescription Strength

### Cetirizine Hydrochloride

### Tablets 10 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

<p>NDC 16571-402-10 Original Prescription Strength</p> <p><b>Cetirizine Hydrochloride</b></p> <p><b>Tablets 10 mg</b></p> <p>Antihistamine</p> <p><b>24 Hour Relief of:</b></p> <p><b>ALLERGY</b></p> <p>Indoor &amp; Outdoor Allergies</p> <p><b>PACK</b></p> <p>100 Tablets</p>	<p><b>Drug Facts (continued)</b></p> <p><b>Other information:</b></p> <ul style="list-style-type: none"><li>• store between 20° to 25°C (68° to 77°F)</li></ul> <p><b>Inactive ingredients</b></p> <p>hypromellose, lactose, magnesium stearate, maize starch, polyethylene glycol, povidone, titanium dioxide</p> <p><b>Questions? call 1-866-562-4597</b></p>	<p>M.L.G1430</p>  <p>16571 40210 6</p> <p>Manufactured for PACK Pharmaceuticals, LLC Buffalo Grove, IL, USA Manufactured by Unique Pharmaceutical Labs. (A Div. of J.B. Chemicals &amp; Pharmaceuticals Ltd.) Mumbai 400 030, India</p> <p>Lot No.: Exp.:</p>
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**CETIRIZINE HYDROCHLORIDE**

cetirizine hydrochloride tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67668-162
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
Cetirizine Hydrochloride (UNII: 64O047KTOA) (Cetirizine - UNII:YO7261ME24)	Cetirizine Hydrochloride	10 mg

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
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

<b>Color</b>	white (White)	<b>Score</b>	no score
<b>Shape</b>	BULLET (Barrel Shaped)	<b>Size</b>	8mm
<b>Flavor</b>		<b>Imprint Code</b>	CTN;10
<b>Contains</b>			

### Packaging

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:67668-162-30	30 in 1 BOTTLE		
2	NDC:67668-162-45	45 in 1 BOTTLE		
3	NDC:67668-162-00	100 in 1 BOTTLE		

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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