

**CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet**  
**Blenheim Pharmacal, Inc.**

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

**Active Ingredients**

**Active Ingredients (in each tablet) Purpose**

Cetirizine HCl 10 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 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.
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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 PACK Pharmaceuticals, LLC  
Buffalo Grove, IL 60089, USA

Manufactured by Unique Pharmaceutical Laboratories (A Div. of J. B. Chemicals & Pharmaceuticals Ltd.),  
Mumbai 400 030, India

### **Cetirizine Hydrochloride Tablets 10 mg Container Label**

Blenheim Pharmacal, Inc.

**NDC 10544-670-30**

Original Prescription Strength

### **Cetirizine Hydrochloride**

#### **Tablets 10 mg**

#### **Antihistamine 24 Hour Relief of:**

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


#### **30 Tablets**

Allergy

Indoor & Outdoor

Allergies

NDC: 10544-670-30 LCN# 000  
MFG: 16571-402-50 Rev 1




**Cetirizine Hydrochloride, Tablets, 10mg**  
**30 Tablets**

Dosage: See package insert  
Store at controlled room temperature  
20°-25°C (68°-77°F)

Store in a tight, light-resistant  
container (See USP). Keep out of the  
reach of children

Each tablet contains:  
Cetirizine HCl 10mg

Mfg: PACK Pharmaceuticals, LLC  
Packaged By: Blenheim Pharmacal, Inc.  
North Blenheim, NY 12131  
Lot #: BP00000000  
Exp Date: 00/00/0000



1054467030+BP00000000+0000

Cetirizine Hydrochloride, Tablets, 10mg  
30 Tablets  
NDC: 10544-670-30 MFG: 16571-402-50  
Lot #: BP00000000 Exp.Date: 00/00/0000

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## CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:10544-670(NDC:16571-402)
<b>Route of Administration</b>	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
HYPROMELLOSES (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

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10544-670-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/23/2015	

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

**Labeler** - Blenheim Pharmacal, Inc. (171434587)

**Registrant** - Blenheim Pharmacal, Inc. (171434587)

**Establishment**

Name	Address	ID/FEI	Business Operations
Blenheim Pharmacal, Inc.		171434587	repack(10544-670)

Revised: 4/2015

Blenheim Pharmacal, Inc.