

**CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet**  
**Lake Erie Medical DBA Quality Care Products LLC**

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

**Active Ingredients**

<b>Active Ingredients (in each tablet)</b>	<b>Purpose</b>
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

### 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

Packaged and Distributed by *Quality Care Products, LLC* 1-800-337-8603



Holland, OH 43528

**CETIRIZINE HCl 10 MG**

Warning: Keep out of children's reach.  
Store at controlled temperature 68-77 degrees F.  
Consult with a physician or see insert for dosage.  
WHITE, BULLET, CTN;10



GTIN: 00335356864304

NDC: 35356-0864-30

Serial:

Lot:

EXP: //

**#30 TABLETS**

ANTIHISTAMINE

CETIRIZINE HCl 10 MG  
#30 TABLETS  
Lot: EXP: //  
NDC: 35356-0864-30

CETIRIZINE HCl 10 MG  
#30 TABLETS  
Lot: EXP: //  
NDC: 35356-0864-30



Each tablet contains Cetirizine Hydrochloride

Mfr: Unique Pharmaceutical Labs. (A Div. of J.B Chemicals & Pharmaceuticals Ltd.)  
Mumbai 400 030, India

## CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35356-864(NDC:16571-402)
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
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>lactose</b> (UNII: J2B2A4N98G)	
<b>magnesium stearate</b> (UNII: 70097M6I30)	
<b>starch, corn</b> (UNII: O8232NY3SJ)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>titanium dioxide</b> (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:35356-864-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2009	
2	NDC:35356-864-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2009	12/01/2009
3	NDC:35356-864-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2009	12/01/2009

## Marketing Information

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

**Labeler** - Lake Erie Medical DBA Quality Care Products LLC (831276758)

## Establishment

Name	Address	ID/FEI	Business Operations
Lake Erie Medical DBA Quality Care Products LLC		831276758	repack(35356-864)

Revised: 4/2020

Lake Erie Medical DBA Quality Care Products LLC