

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

Cetirizine Hydrochloride Tablets, 10 mg, Allergy

Active Ingredients

Cetirizine HCl 10 mg.....	Antihistamine
Ingredients (in each tablet)	Active 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

if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine. **Do Not Use**

liver or kidney disease. Your doctor should determine if you need a different dose. **Ask a doctor before use if you have**

taking tranquilizers or sedatives. **Ask a doctor or pharmacist before use if you are**

When using this product

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

if an allergic reaction to this product occurs. Seek medical help right away. **Stop use and ask a doctor**

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	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 severe
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	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

Inactive Ingredients

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

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 5 MG

Warning: Keep out of children's reach.
Store at 68 to 77 degrees F.
Consult with a physician.



GTIN: 00355700331306

WHITE, BARREL SHAPED, CTN;5

NDC: 55700-0331-30

#30 TABLETS

Serial:

Lot:

Antihistamine

EXP: //

Each tablet contains Cetirizine Hydrochloride

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

Distributed by: Rising Pharmaceuticals, Inc., Saddle Brook, NJ 07663



CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55700-331(NDC:16571-401)
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
hypromelloses (UNII: 3NXW29V3WO)	
lactose (UNII: J2B2A4N98G)	
magnesium stearate (UNII: 70097M6I30)	

starch, corn (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (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:55700-331-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	07/24/2015	

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(55700-331)

Revised: 9/2019

Lake Erie Medical DBA Quality Care Products LLC