CETIRIZINE - cetirizine hydrochloride tablet Life Line Home Care Services, Inc.

Cetirizine HCL 10mg Tablet

Active ingredient (in each tablet)

Cetirizine HCl 10 mg

Purpose

Antihistamine

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

- drowsiness 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 a Poison Control Center right away.

Directions

6 years and over	one 10 mg tablet once daily; do not take more than
adults and children	one 10 mg tablet in 24 hours. A 5 mg product may
	be appropriate for less severe symptoms.
adults 65 years and over	ask a doctor
children under 6 years of age	ask a doctor
consumers with liver or	ask a doctor
kidney disease	

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.

Cetirizine HCL 10mg Tablet

CETIRIZINE HCL (Cetirizine Hydrochloride) Tablets

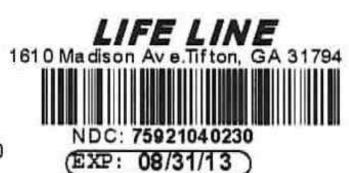
10 MG

CETIRIZINE HCL 10 MG QTY:30 TABLETS MFG: PACK

CETIRIZINE HCL MFG LOT: PUZ1010

MFG NDC: 16571040210

PRGD: BUT 12/07/11 10:25 AM



CETIRIZINE

cetirizine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75921-402(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		
HYPROMELLOSES (UNII: 3NXW29 V3WO)			
LACTOSE (UNII: J2B2A4N98G)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
STARCH, CORN (UNII: O8232NY3SJ)			
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)			
PO VIDO NE (UNII: FZ989 GH9 4E)			
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)			

Product Characteristics			
Color	white	Score	no score
Shape	BULLET (Barrel Shaped)	Size	8 mm
Flavor		Imprint Code	CTN;10
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75921-402-30	30 in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077829	02/03/2012	

Labeler - Life Line Home Care Services, Inc. (844985374)

Establishment			
Name	Address	ID/FEI	Business Operations
Life Line Home Care Services, Inc.		844985374	REPACK, RELABEL

Revised: 2/2012 Life Line Home Care Services, Inc.