CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet
NuCare Pharmaceuticals, Inc.

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 machinary.

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

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

Other Information

store between 20° to 25°C (68° to 77°F)

Inactive Ingredients

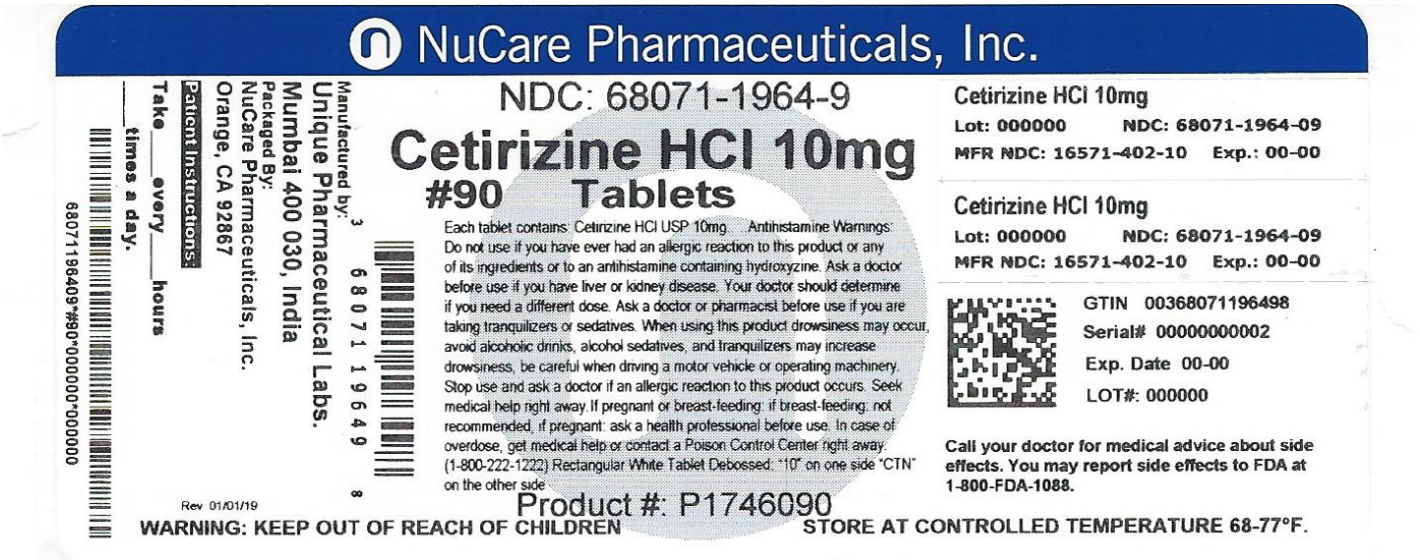
Hypromellose, lactose, magnesium stearate, maize starch, polyethylene glycol, povidone, titanium dioxide.

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

cetirizine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68071-1964(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**
STARCH, CORN (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOL (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:68071-1964-1	10 in 1 BOTTLE; Type 0: Not a Combination Product	02/21/2017	
2	NDC:68071-1964-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/21/2017	
3	NDC:68071-1964-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/21/2017	
4	NDC:68071-1964-7	7 in 1 BOTTLE; Type 0: Not a Combination Product	02/21/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

ANDA	ANDA077829	10/01/2009	

Labeler - NuCare Pharmaceuticals, Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals, Inc.		010632300	repack(68071-1964)

Revised: 4/2021 NuCare Pharmaceuticals, Inc.