CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet
Drug Ocean LLC

Cetirizine Hydrochloride Tablets USP , 5 mg
Drug Facts

Active Ingredients

Active Ingredient (in each tablet)	**Purpose**
Cetirizine HCl USP 5 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. (1-800-222-1222)

Directions

Adults and children 6 years and over	1 to 2 tablets once daily depending upon severity of symptoms; do not take more than 2 tablets in 24 hours.

Adults 65 years and over	1 tablet1 tablet once a day; do not take more than 1 tablet in 24 hours.
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) [See USP Controlled Room Temperature.]

Inactive Ingredients

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

Questions?

Call 1-866-562-4597

Manufactured for:

Drug Ocean, LLC
221 River street, Suite 9051,
Hoboken, NJ 07030

Manufactured by:

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

M.L. G/1430

Rev. 11-2016

Cetirizine Hydrochloride Tablets 5 mg Container Label

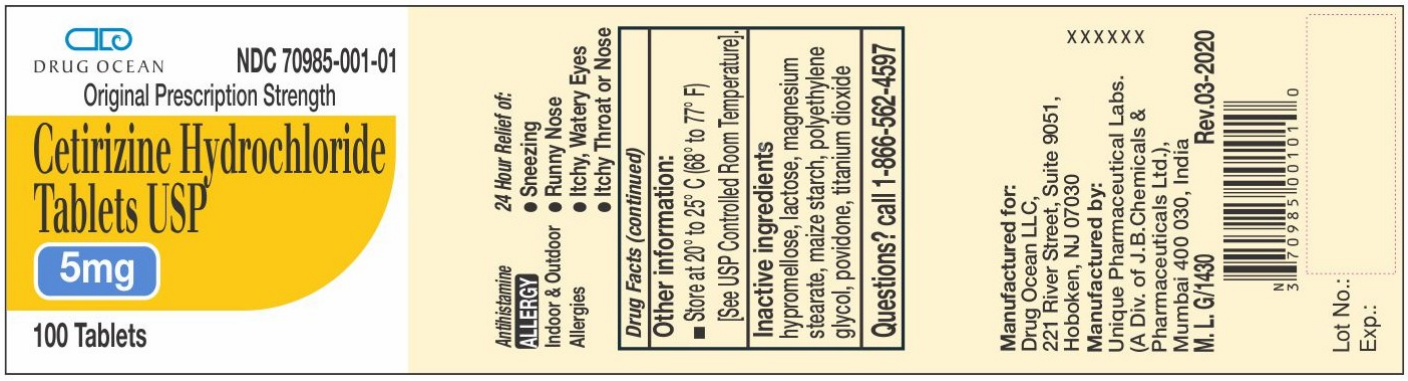
DRUG OCEAN NDC 70985-001-01

Original Prescription Strength

Cetirizine Hydrochloride
Tablets USP

5 mg

100 Tablets



CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70985-001
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 (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:70985-001-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/08/2016	
2	NDC:70985-001-02	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/08/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077829	11/08/2016	

Labeler - Drug Ocean LLC (080381835)

Registrant - Unique Pharmaceutical Laboratories (917165052)

Establishment

Name	Address	ID/FEI	Business Operations
Unique Pharmaceutical Laboratories		650434645	MANUFACTURE(70985-001)

Revised: 3/2020 Drug Ocean LLC