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
1 Bridge Plaza, North Central Road,

6th Floor, Suite 675,

Fort Lee, NJ 07024

Manufactured by:

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

M.L. G/1430

Rev. 12/2023

Cetirizine Hydrochloride Tablets 5 mg Container Label

DRUG OCEAN NDC 70985-001-01

Original Prescription Strength

Cetirizine Hydrochloride

Tablets USP

5 mg

100 Tablets

DRUG OCEAN NDC 70985-001-02

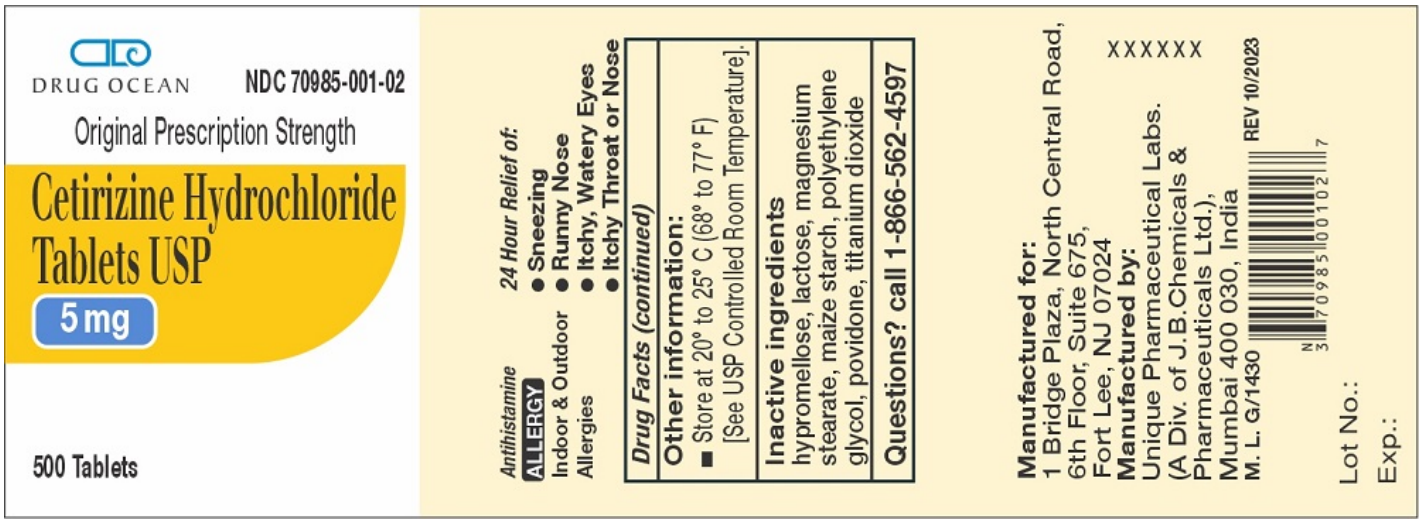
Original Prescription Strength

Cetirizine Hydrochloride

Tablets USP

5 mg

500 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: 3WQ0SDW1A)	
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)