### CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet Drug Ocean LLC

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Cetirizine Hydrochloride Tablets USP 10 mg

**Drug Facts** 

#### **Active Ingredients**

## Active Ingredient (in each tablet) Purpose

Cetirizine HCI USP 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. (1-800-222-1222)

#### **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) [See USP Controlled Room Temperature]

#### **Inactive Ingredients**

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

#### Questions?

Call 1-866-333-9792

#### **DRUG OCEAN NDC 70985-002-01**

Original Prescription Strength

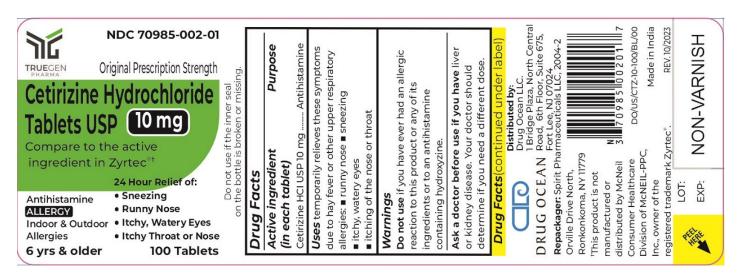
#### **Cetirizine Hydrochloride**

#### **Tablets USP**

#### 10 mg

6 yrs& older

100 Tablets



#### **DRUG OCEAN NDC 70985-002-02**

Original Prescription Strength

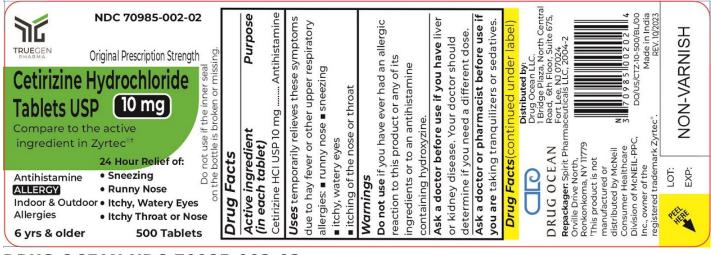
#### Cetirizine Hydrochloride

#### Tablets USP

10 mg

6 yrs& older

500 Tablets



#### **DRUG OCEAN NDC 70985-002-03**

Original Prescription Strength

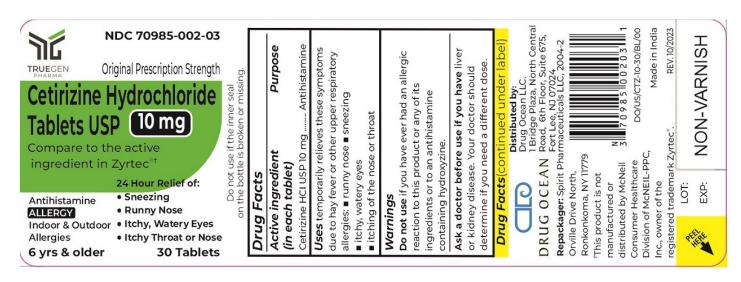
#### Cetirizine Hydrochloride

#### Tablets USP

10 mg

6 yrs& older

30 Tablets



#### **DRUG OCEAN NDC 70985-002-04**

Original Prescription Strength

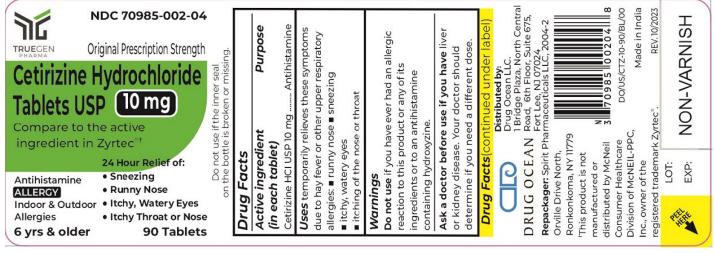
#### Cetirizine Hydrochloride

#### Tablets USP

10 mg

6 yrs& older

90 Tablets



#### **DRUG OCEAN NDC 70985-002-05**

Original Prescription Strength

#### Cetirizine Hydrochloride

#### Tablets USP

10 mg

6 yrs& older

300 Tablets

#### NDC 70985-002-05

Original Prescription Strength

# Cetirizine Hydrochloride Tablets USP 10 mg

Compare to the active ingredient in Zyrtec<sup>®†</sup>

#### 24 Hour Relief of:

#### **Antihistamine** ALLERGY

- Sneezing Runny Nose
- Indoor & Outdoor Itchy, Watery Eyes
- Itchy Throat or Nose Allergies **300 Tablets**

6 yrs & older

on the bottle is broken or missing. Do not use if the inner seal

# **Drug Facts**

Purpose

**Active ingredient** 

Cetirizine HCI USP 10 mg (in each tablet)

Antihistamine Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ runny nose ■ sneezing

■ itching of the nose or throat ■ itchy, watery eyes

Do not use if you have ever had an allergic ingredients or to an antihistamine Warnings

Ask a doctor before use if you have liver reaction to this product or any of its containing hydroxyzine.

determine if you need a different dose. or kidney disease. Your doctor should

Drug Facts (continued under labe

Distributed by:

DRUG OCEAN Road, 6th Floor, Suite 675, Fort Lee, NJ 07024

Repackager: Spirit Pharmaceuticals LLC, 2004-2

Ronkonkoma, NY 11779 Orville Drive North, This product is not manufactured or

Inc., owner of the registered trademark Zyrtec". Consumer Healthcare Division of McNEIL-PPC, distributed by McNeil

DO/US/CTZ-10-300/BL/00 Made in India REV. 10/2023

EXP: LOT:

NON-VARNISH

#### CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70985-002	
Route of Administration	ORAL			

Active Ingredient/Active Moiety		
Ingredient Name	<b>Basis of Strength</b>	Strength
CETIRIZINE HYDROCHLORIDE (UNII: 640047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZ INE HYDROCHLORIDE	10 mg

Inactive Ingredients		
Ingredient Name	Strength	
LACTOSE (UNII: J2B2A4N98G)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
STARCH, CORN (UNII: O8232NY3SJ)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POVIDONE (UNII: FZ989GH94E)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		

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

Packaging		
	Mayleating Ctart	Maulcating Fuel

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70985-002- 01			
2	NDC:70985-002- 02	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/08/2016	
3	NDC:70985-002- 03	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/05/2021	
4	NDC:70985-002- 04	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/05/2021	
5	NDC:70985-002- 05	300 in 1 BOTTLE; Type 0: Not a Combination Product	08/05/2021	

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	<b>Business Operations</b>	
Unique Pharmaceutical Laboratories		650434645	manufacture(70985-002)	

Revised: 12/2023 Drug Ocean LLC