CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet
Umasuto, LLC

Cetirizine Hydrochloride Tablets USP 10 mg

Drug Facts

Active Ingredient (in each tablet)
Cetirizine HCl USP 10 mg

Pupose

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

- 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 at 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 1-866-768-0551

Manufactured by:

Unique Pharmaceutical Laboratories

(A Div. of J. B. Chemicals & Pharmaceuticals Ltd.),

Mumbai 400 030, India

Distributed by:

Umasuto, LLC

14130 Minnesota Avenue, Bonner Springs,

KS 66012

Issued 03/2025

PRINCIPAL DISPLAY PANEL-100'S COUNT

UMASUTO NDC 85293-001-01

Original Prescription Strength

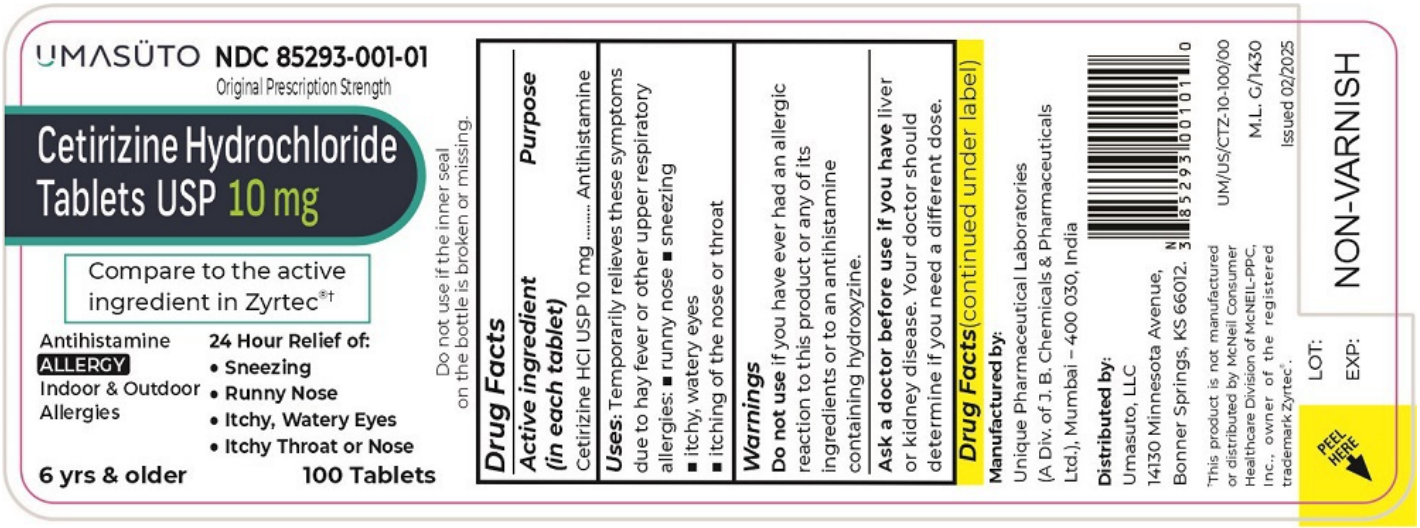
Cetirizine Hydrochloride Tablets USP 10 mg

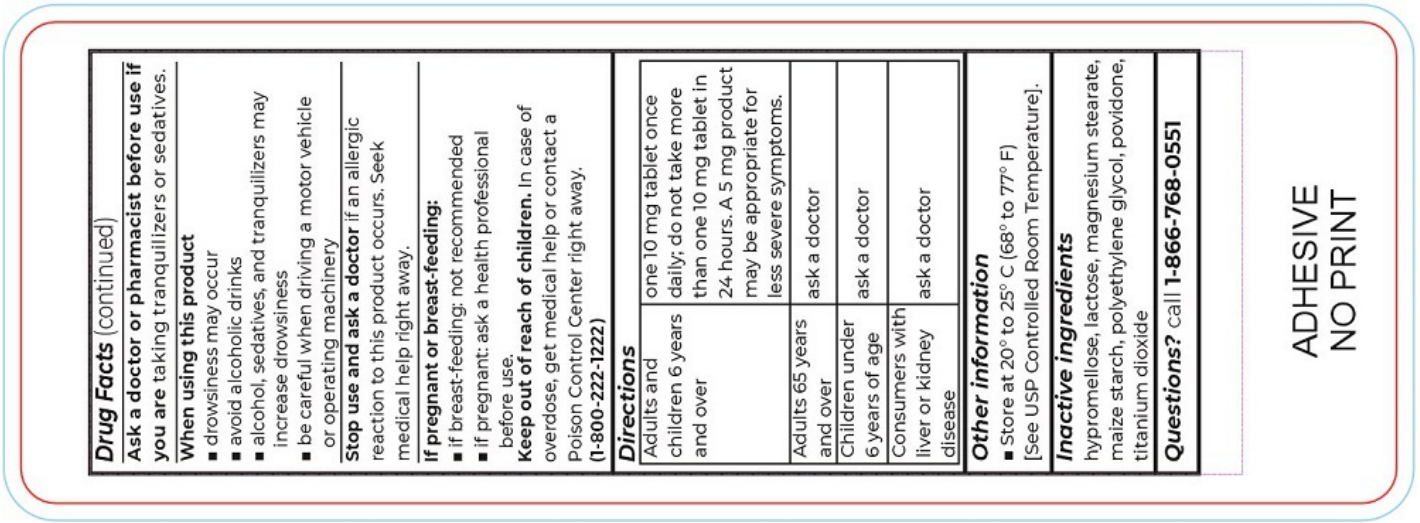
Compare to the active ingredient in Zyrtec

Antihistamine
ALLERGY
Indoor & Outdoor Allergies

24 Hour Relief of:
•Sneezing
•Runny Nose
•Itchy, Watery Eyes
•Itchy Throat or Nose

6 yrs& older 100 Tablets





CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:85293-001
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
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
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

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85293-001-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/04/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077829	03/04/2025	

Labeler - Umasuto, LLC (111784700)

Registrant - Unique Pharmaceutical Laboratories (917165052)

Establishment

Name	Address	ID/FEI	Business Operations
Unique Pharmaceutical Laboratories		650434645	manufacture(85293-001) , analysis(85293-001)