

CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet
RedPharm Drug

Cetirizine 10 mg

ACTIVE INGREDIENTS

Active Ingredients (in each tablet)

Purpose

Cetirizine HCl USP 10 mg.....Antihistamine

PURPOSE

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 DOCTOR

Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.

ASK DOCTOR/PHARMACIST

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.

WHEN USING THIS PRODUCT

- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery.

STOP USE

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 severe 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 1-866-562-4597

Manufactured by:

Unique Pharmaceutical Labs.

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

Distributed by:

Rising Pharmaceuticals, Inc.
Saddle Brook, NJ 07663

M. L. G/1430 May 2018

120005

PRINCIPAL DISPLAY PANEL-100'S COUNT

———PRINCIPAL DISPLAY PANEL———

Rising® 16571-402-10
Original Prescription Strength
Cetirizine Hydrochloride Tablets USP 10 mg
6 yrs & older
100 Tablets

	<p>Antihistamine ALLERGY</p> <p>24 Hour Relief of: ● Sneezing ● Runny Nose ● Itchy, Watery Eyes ● Itchy Throat or Nose</p> <p>Indoor & Outdoor Allergies</p> <p>Drug Facts (continued)</p> <p>Other information: ■ Store at 20° to 25° C (68° to 77° F) [See USP Controlled Room Temperature].</p> <p>Inactive ingredients: hypromellose, lactose, magnesium stearate, maize starch, polyethylene glycol, povidone, titanium dioxide</p> <p>Questions? call 1-866-562-4597</p>	<p>123412 Manufactured by: Unique Pharmaceutical Labs. (A Div. of J.B.Chemicals & Pharmaceuticals Ltd.), Mumbai 400 030, India</p> <p>Distributed by: Rising Pharmaceuticals, Inc. Saddle Brook, NJ 07663 M. L. G/1430 May 2018</p> <p>Lot No. _____ Exp.: _____</p>
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PRINCIPAL DISPLAY PANEL-500'S COUNT

PRINCIPAL DISPLAY PANEL

Rising® 16571-402-50
 Original Prescription Strength
 Cetirizine Hydrochloride Tablets USP 10 mg
 6 yrs & older
 500 Tablets

	<p>Antihistamine ALLERGY Indoor & Outdoor Allergies</p> <p>24 Hour Relief of: ● Sneezing ● Runny Nose ● Itchy, Watery Eyes ● Itchy Throat or Nose</p> <p>Drug Facts (continued)</p> <p>Other information: ■ Store at 20° to 25° C (68° to 77° F) [See USP Controlled Room Temperature].</p> <p>Inactive ingredients hypromellose, lactose, magnesium stearate, maize starch, polyethylene glycol, povidone, titanium dioxide</p> <p>Questions? call 1-866-562-4597</p>	<p>123413 16571 40250 2</p> <p>Manufactured by: Unique Pharmaceutical Labs. (A Div. of J.B.Chemicals & Pharmaceuticals Ltd.), Mumbai 400 030, India</p> <p>Distributed by: Rising Pharmaceuticals, Inc. Saddle Brook, NJ 07663</p> <p>M. L. G/1430 May 2018</p> <p>Lot No. _____ Exp.: _____</p>
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PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



NDC: 67296-1085-3
CETIRIZINE HCL

Rx Only

10MG
 30 Tablets

Lot: Y99038X1

Exp: 06/21

(01)00367296108538
 (21)100000000000404
 (17)210630
 (10)Y99038X1

Usual adult dosage: See package insert
 Store at controlled room temperature: 20-25 C (68-77 F)

Mfg: Unique Pharmaceutical Laboratories
 Mumbai 400 030 India
 16571-402-50

Dist. by: Redpharm Drug Eden Prairie, MN 55344

SIN 87641



CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67296-1085(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
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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:67296-1085-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	09/21/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077829	09/21/2020	

Labeler - RedPharm Drug (828374897)

Establishment

Name	Address	ID/FEI	Business Operations
EPM Packaging		079124340	repack(67296-1085)

Revised: 1/2022

RedPharm Drug