

CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet
Rising Pharma Holdings, Inc.

Cetirizine Hydrochloride Tablets USP
5 mg, Allergy

Active Ingredient (in each tablet)

Cetirizine HCl USP 5 mg

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 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

- 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 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

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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 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 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 1-844-874-7464

Manufactured by:

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

Distributed by:

Rising Pharma Holdings, Inc.
 East Brunswick, NJ 08816

M.L. G/1430 Jul. 2020

129575

PRINCIPAL DISPLAY PANEL-100'S COUNT

Rising NDC 16571-401-10

Original Prescription Strength

Cetirizine Hydrochloride Tablets USP 5 mg

Antihistamine

ALLERGY

Indoor & Outdoor Allergies

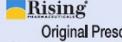
24 Hour Relief of:

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose

100 Tablets

T10 - M.L. G/1430

 <p>NDC 16571-401-10</p> <p>Original Prescription Strength</p> <h1>Cetirizine Hydrochloride Tablets USP</h1> <p>5mg</p> <p>100 Tablets</p>	<p>24 Hour Relief of:</p> <ul style="list-style-type: none"> • Sneezing • Runny Nose • Itchy, Watery Eyes • Itchy Throat or Nose <p>Antihistamine ALLERGY</p> <p>Indoor & Outdoor Allergies</p> <p>Drug Facts (continued)</p> <p>Other information:</p> <ul style="list-style-type: none"> ■ Store at 20° to 25° C (68° to 77° F) (See USP Controlled Room Temperature). <p>Inactive ingredients</p> <p>hypromellose, lactose, magnesium stearate, maize starch, polyethylene glycol, povidone, titanium dioxide</p> <p>Questions? call 1-844-874-7464</p>	<p>126407</p> <p>Manufactured by: Unique Pharmaceutical Labs. (A Div. of J.B.Chemicals & Pharmaceuticals Ltd.), Mumbai 400 030, India</p> <p>Distributed by: Rising Pharma Holdings, Inc. East Brunswick, NJ 08816</p> <p>M. L. G/1430 Jul. 2020</p>  <p>Lot No.: _____</p> <p>Exp.: _____</p>
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T20 - M.L. G/25/2188

 <p>NDC 16571-401-10</p> <p>Original Prescription Strength</p> <h1>Cetirizine Hydrochloride Tablets USP</h1> <p>5mg</p> <p>100 Tablets</p>	<p>24 Hour Relief of:</p> <ul style="list-style-type: none"> • Sneezing • Runny Nose • Itchy, Watery Eyes • Itchy Throat or Nose <p>Antihistamine ALLERGY</p> <p>Indoor & Outdoor Allergies</p> <p>Drug Facts (continued)</p> <p>Other information:</p> <ul style="list-style-type: none"> ■ Store at 20° to 25° C (68° to 77° F) (See USP Controlled Room Temperature). <p>Inactive ingredients</p> <p>hypromellose, lactose, magnesium stearate, maize starch, polyethylene glycol, povidone, titanium dioxide</p> <p>Questions? call 1-844-874-7464</p>	<p>129575</p> <p>Manufactured by: Unique Pharmaceutical Labs. (A Div. of J.B.Chemicals & Pharmaceuticals Ltd.), Mumbai 400 030, India</p> <p>Distributed by: Rising Pharma Holdings, Inc. East Brunswick, NJ 08816</p> <p>M. L. G/25/2188 Jul. 2020</p>  <p>Lot No.: _____</p> <p>Exp.: _____</p>
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CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:16571-401	
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 (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:16571-401-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2009	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA077829	10/01/2009		

Labeler - Rising Pharma Holdings, Inc. (116880195)

Registrant - Unique Pharmaceutical Laboratories (917165052)

Establishment

Name	Address	ID/FEI	Business Operations
Unique Pharmaceutical Laboratories		650434645	ANALYSIS(16571-401) , MANUFACTURE(16571-401)

Establishment

Name	Address	ID/FEI	Business Operations
Unique Pharmaceutical Laboratories		864354608	analysis(16571-401) , manufacture(16571-401)