

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

Cetirizine Hydrochloride Tablets USP, 10 mg, Allergy

Active Ingredient (in each tablet)

Cetirizine HCl USP 10 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 a 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 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 1-844-874-7464

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

126406

PRINCIPAL DISPLAY PANEL-100'S COUNT

Rising® 16571-402-10

Original Prescription Strength

**Cetirizine Hydrochloride Tablets USP 10 mg
6 yrs & older**

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 style="text-align: right;">NDC 16571-402-10</p> <p style="text-align: center;">Original Prescription Strength Cetirizine Hydrochloride Tablets USP</p> <p style="text-align: center;">10mg</p> <p>6 yrs & older 100 Tablets</p>	<p style="text-align: center;">24 Hour Relief of:</p> <ul style="list-style-type: none"> • Sneezing • Runny Nose • Itchy, Watery Eyes • Itchy Throat or Nose <p style="text-align: center;">Antihistamine ALLERGY</p> <p style="text-align: center;">Indoor & Outdoor Allergies</p>	<p style="text-align: center;">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 hypromellose, lactose, magnesium stearate, maize starch, polyethylene glycol, povidone, titanium dioxide</p> <p>Questions? call 1-844-874-7464</p>	<p>126406</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 16571-402-10</p> <p>Original Prescription Strength</p> <h1>Cetirizine Hydrochloride Tablets USP</h1> <p>10mg</p> <p>6 yrs & older 100 Tablets</p>	<p>Antihistamine ALLERGY Indoor & Outdoor Allergies</p> <p>24 Hour Relief of:</p> <ul style="list-style-type: none"> • Sneezing • Runny Nose • Itchy, Watery Eyes • Itchy Throat or Nose <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 hypromellose, lactose, magnesium stearate, maize starch, polyethylene glycol, povidone, titanium dioxide</p> <p>Questions? call 1-844-874-7464</p>	<p>129576</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 M. L. G/25/2188 Jul. 2020</p>  <p>Lot No.:</p> <p>Exp.:</p>
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PRINCIPAL DISPLAY PANEL-500'S COUNT

Rising® 16571-402-50

Original Prescription Strength

Cetirizine Hydrochloride Tablets USP 10 mg
6 yrs & older

Antihistamine

ALLERGY


Indoor & Outdoor Allergies

24 Hour Relief of:

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

500 Tablets

T10 - M.L. G/1430



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


Antihistamine ALLERGY
Indoor & Outdoor Allergies

24 Hour Relief of:
● Sneezing
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Drug Facts (continued)
Other information:
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Inactive ingredients
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Questions? call 1-844-874-7464




126405

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Distributed by:
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East Brunswick, NJ 08816

M. L. G/1430 Jul 2020

Lot No.:
Exp.:



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

Antihistamine ALLERGY
Indoor & Outdoor Allergies

24 Hour Relief of:
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Drug Facts


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OPEN FOR FULL INFORMATION →

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T20 - M.L. G/25/2188



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


Antihistamine ALLERGY
Indoor & Outdoor Allergies

24 Hour Relief of:
● Sneezing
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Original Prescription Strength
Cetirizine Hydrochloride
Tablets USP

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6 yrs & older

500 Tablets

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CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	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: O8232NY35J)	
polyethylene glycol (UNII: 3WJQ0SDW1A)	
povidone (UNII: FZ989GH94E)	
titanium dioxide (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (White)	Score	no score
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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:16571-402-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2009	
2	NDC:16571-402-50	500 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	MANUFACTURE(16571-402) , analysis(16571-402)

Establishment

Name	Address	ID/FEI	Business Operations
Unique Pharmaceutical Laboratories		864354608	analysis(16571-402) , manufacture(16571-402)

Revised: 2/2024

Rising Pharma Holdings, Inc.