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

Cetirizine Hydrochloride Tablets USP, 10 mg, Allergy

Active Ingredient (in each tablet)

Cetirizine HCI 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

- 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 a Poison Control Center right away. (1-800-222-1222)

Directions

Adults and	one 10 mg tablet once daily, do not take more than one 10	
children 6	mg tablet in 24 hours. A 5 mg product may be appropriate	
years and over	for less severe symptoms.	
Adults 65 years	Ask a doctor	
and over	ASK & doctor	
Children under	Ask a doctor	
6 years of age	ASK & GOCTOL	
Consumers		
with liver or	Ask a doctor	
kidney disease		

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 126406

PRINCIPAL DISPLAY PANEL-100'S COUNT

Rising® 16571-402-10

Original Prescription Strength

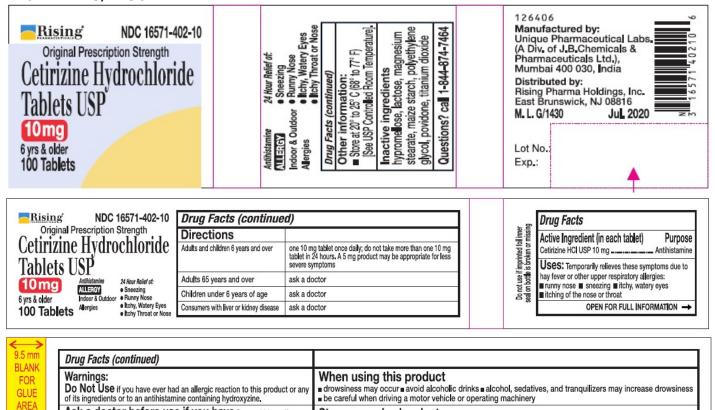
Cetirizine Hydrochloride Tablets USP 10 mg 6 yrs & older

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



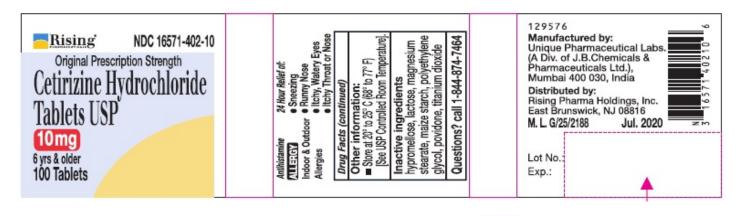
Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.

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) →

Ask a doctor before use if you have liver or kidney disease.

Ask a doctor or pharmacist before use if you are taking





Drug Facts (continued)		
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	

Drug Facts	
Active Ingredient (in each tablet) Cetirizine HCI USP 10 mg	Purpose Antihistamine
Uses: Temporarily relieves these syn hay fever or other upper respiratory alle ■ runny nose ■ sneezing ■ itchy, wate ■ itching of the nose or throat	rgies:
OPEN FOR FULL INFO	RMATION -

4
9.5 mm
BLANK
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GLUE
AREA

Drug Facts (continued)	
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.	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
Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.	Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.
Ask a doctor or pharmacist before use if you are taking	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)

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:

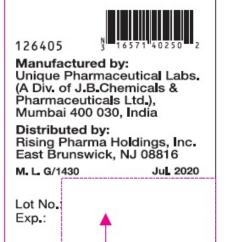
- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose

500 Tablets

T10 - M.L. G/1430









6 yrs & older 500 Tablets

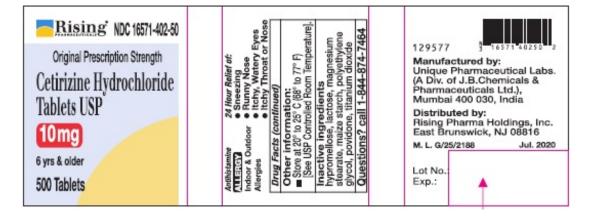
Antihistamine	24 Hour Relief of:
ALLERGY	 Sneezing
Indoor & Outdoor	 Runny Nose
Alergies	 Itchy, Watery Eyes
recigios	• Itchy Throat or Nose

Drug Facts (continued)		
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	
Chi l dren under 6 years of age	ask a doctor	
Consumers with liver or kidney disease	ask a doctor	

ner sing	Drug Facts
	Active Ingredient (in each tablet) Purpose Cetinizine HCI USP 10 mg Antihistamine
t use if bottle	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 OPEN FOR FULL INFORMATION →

Drug Facts (continued)	
Warnings: Do Not Use if you have ever had an allergic reaction to this product or any	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
of its ingredients or to an antihistamine containing hydroxyzine.	Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.
Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.	If pregnant or breast-feeding: ∎ if breast-feeding: not recommended ∎ if pregnant: ask a health professional before use.
Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.	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) →

T20 - M.L. G/25/2188





Indoor & Outdoor · Runny Nose Itchy, Watery Eyes 500 Tablets

Itchy Throat or Nose

Drug Facts (continued)		
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	

Drug Facts 9 0 ■ itching of the nose or throat Sea D OPEN FOR FULL INFORMATION ->

Drug Facts (continued)	
Warnings: Do Not Use if you have ever had an allergic reaction to this product or any	When using this product a drowsiness may occur avoid alcoholic drinks a alcohol, sedatives, and tranquilizers may increase drowsiness a be careful when driving a motor vehicle or operating machinery
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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: O8232NY3SJ)			
polyethylene glycol (UNII: 3WJQ0SDW1A)			
povidone (UNII: FZ 989GH94E)			
titanium dioxide (UNII: 15FIX9V2JP)			

Color WHITE (White) Score no score

Shape	BULLET (Barrel Shaped)	Size	8mm
Flavor		Imprint Code	CTN;10
Contains			

Packaging				
# Item Code	Item Code Package Description		Marketing End Date	
1 NDC:16571-402-	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.