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

Cetirizine Hydrochloride Tablets USP
5 mg, Allergy

ACTIVE INGREDIENTS (IN EACH TABLET)

Cetirizine HCl USP 5 mg

PURPOSE

Antihistimine

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

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

- 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

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 6years 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 July 2020

129575

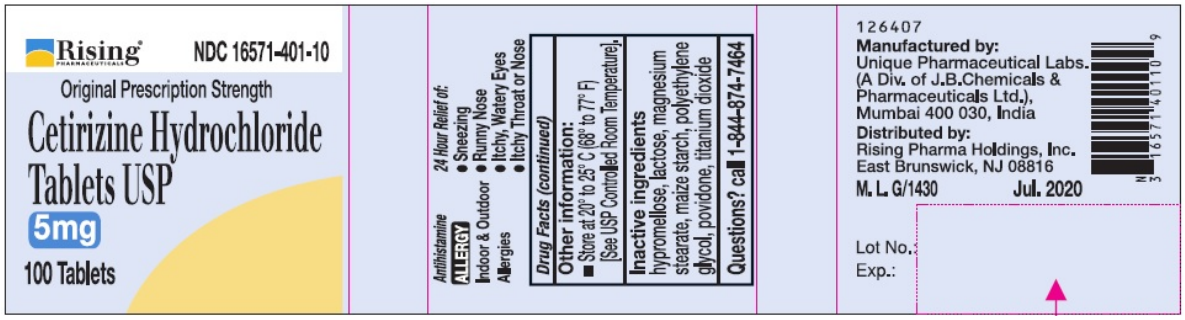
Cetirizine Hydrochloride Tablets USP 5 mg

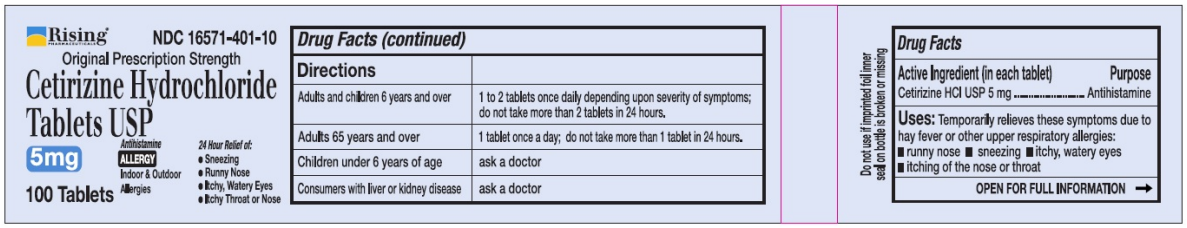
Rising NDC 16571-401-10

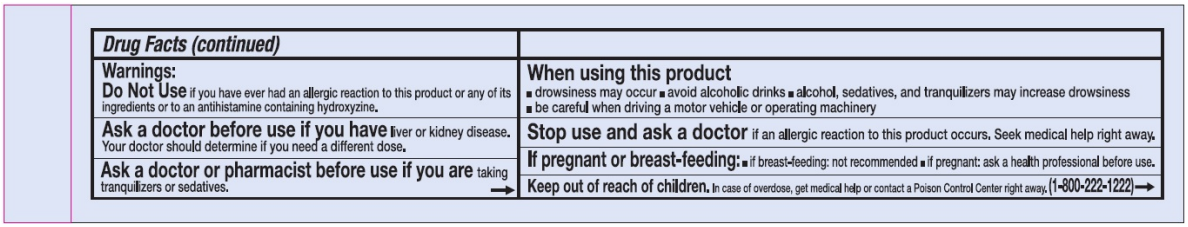
Original Prescription Strength

Cetirizine Hydrochloride
Tablets 5 mg

100 Tablets







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: 3WQ0SDW1A)	
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. (835513529)

Registrant - Unique Pharmaceutical Laboratories (917165052)

Establishment

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

Revised: 11/2021 Rising Pharma Holdings, Inc.