CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet
Proficient Rx LP

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 1-866-562-4597

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

120004

Repackaged By;

Proficient Rx LP

Thousand Oaks 91320

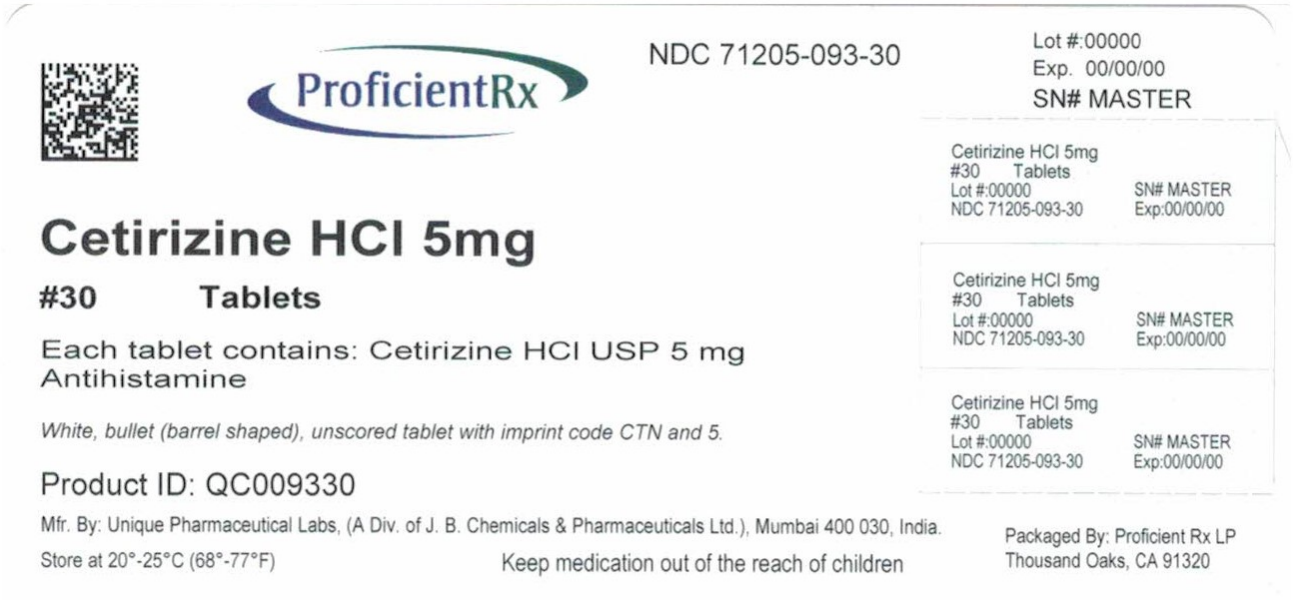
Cetirizine Hydrochloride Tablets USP 5 mg

NDC 71205-093-30

Original Prescription Strength

Cetirizine Hydrochloride
Tablets 5 mg

30 Tablets



CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71205-093(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**
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
magnesium stearate (UNII: 70097M6I30)	
starch, corn (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

POVIDONE, UNSPECIFIED (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:71205-093-15	15 in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2018	
2	NDC:71205-093-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2018	
3	NDC:71205-093-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2018	
4	NDC:71205-093-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077829	10/01/2009	

Labeler - Proficient Rx LP (079196022)

Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	REPACK(71205-093) , RELABEL(71205-093)