

CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet
ST. MARY'S MEDICAL PARK PHARMACY

Cetirizine Hydrochloride Tablets USP, 10 mg, Allergy

ACTIVE INGREDIENTS

Active Ingredients (in each tablet)

Purpose

Cetirizine HCl USP 10 mg.....Antihistamine

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 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

- 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

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.

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

NDC 60760-886-30

Cetirizine Hydrochloride Tablets USP 10mg

QTY: 30
LOT# XXXXXXX
EXP XX-XX
RX# ????????

MANUFACTURED BY:
Unique Pharmaceutical Labs.
Mumbai 400 030, India

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QTY: 30
RX# ????????

NDC 60760-886-30
LOT# XXXXXXX
EXP XX-XX

USE AS DIRECTED



Rx only STORE AT CONTROLLED ROOM TEMPERATURE 15°- 30° C (59°-86°F)

CETIRIZINE HYDROCHLORIDE		
cetirizine hydrochloride tablet		
Product Information		
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC:60760-886(NDC:16571-402)
Route of Administration	ORAL	
Active Ingredient/Active Moiety		
	Ingredient Name	Basis of 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: 70097M6I3O)	
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	8mm
Flavor		Imprint Code	CTN;10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60760-886-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/17/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077829	01/17/2023	

Labeler - ST. MARY'S MEDICAL PARK PHARMACY (063050751)

Establishment

Name	Address	ID/FEI	Business Operations
ST. MARY'S MEDICAL PARK PHARMACY		063050751	relabel(60760-886) , repack(60760-886)

Revised: 1/2023

ST. MARY'S MEDICAL PARK PHARMACY