

CETIRIZINE HYDROCHLORIDE (ALLERGY RELIEF) - cetirizine hydrochloride tablet
Fred's, Inc.

Drug Facts

Active ingredient (in each tablet)

Cetirizine hydrochloride 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 between 20° to 25°C (68° to 77°F)
- **TAMPER EVIDENT: DO NOT USE IF SEAL OVER BOTTLE OPENING IS BROKEN OR MISSING.**

Inactive Ingredients

colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide.

Questions?

call **1-855-274-4122**

Keep the carton. It contains important information.

Distributed by:

**fred's, Inc.,
4300 NEW GETWELL RD,
MEMPHIS, TN 38118
www.fredsinc.com**

Code: TS/DRUGS/19/1993

Made in India

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 10 mg (30's Tablet Container Carton Label)

fred's Pharmacy

NDC 55315-007-09

24 Hour Relief of:

- Sneezing
- Runny Nose
- Itchy, Watery Eyes

- Itchy Throat or Nose

ALLERGY RELIEF Indoor & Outdoor Allergies

Cetirizine Hydrochloride Tablets USP 10 mg
Antihistamine
Original Prescription Strength

30 TABLETS
10 MG EACH

Compare To The Active Ingredient of Zyrtec®*



CETIRIZINE HYDROCHLORIDE (ALLERGY RELIEF)

cetirizine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55315-007
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETIRIZINE HYDRO CHLORIDE (UNII: 64O047KTOA) (CETIRIZINE -	CETIRIZINE	10 mg

UNII:YO7261ME24)	HYDROCHLORIDE	10 mg
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Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (White to Off-white)	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	X;36
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55315-007-09	1 in 1 CARTON	08/05/2015	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090760	08/05/2015	

Labeler - Fred's, Inc. (005866116)

Registrant - Aurobindo Pharma Limited (650082092)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		918917642	ANALYSIS(55315-007) , MANUFACTURE(55315-007)