

CETIRIZINE HYDROCHLORIDE - cetirizine hydrochloride allergy tablet
Cardinal Health

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**

DISTRIBUTED BY
 CARDINAL HEALTH
 DUBLIN, OHIO 43017
 www.myleader.com
 1-800-200-6313

Made in India

Code: TS/DRUGS/19/1993

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 10 mg (365's Tablets Bottle)

LEADER™

NDC 70000-0047-1

**Original Prescription Strength
 All Day Allergy**

**Cetirizine Hydrochloride Tablets
USP, 10 mg | Antihistamine**

**COMPARE TO
ZYRTEC®
active ingredient***

**Indoor and
Outdoor Allergies
24-Hour Relief of:
Sneezing; Runny Nose; Itchy,
Watery Eyes; Itchy Throat or Nose**

**365 TABLETS
10 mg EACH**

Top Layer Printing side

LEADER²

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COMPARE TO
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active ingredient*

100%
Money Back
Guarantee

Return to place of purchase.

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Uses
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Code: TS/DRUGS/19/1993

LM-4096

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Made in India

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REV. 4/20

CIN 5605258

FPO

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Lift Here for Drug Facts

* Lot: XXXXXXXXX
EXP: MM/YYYY
Prefix & Variables of Lot, EXP shall be printed online during packing.

Top Layer Adhesive side

Drug Facts (continued)

■ 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

Drug Facts (continued)

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Gluing Area

Base Layer

Gluing Area

Drug Facts (continued)

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Questions? call 1-855-274-4122

LM-4096

*This product is not manufactured or distributed by McNeil Consumer Healthcare, Division of McNeil-PPC, Inc., owner of the registered trademark Zyrtec®.

A/s: 120 x 45 mm

CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride allergy tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0047
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
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:70000-0047-1	365 in 1 BOTTLE; Type 0: Not a Combination Product	03/26/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090760	03/26/2020	

Labeler - Cardinal Health (063997360)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 6/2021

Cardinal Health