

**CETIRIZINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE -
cetirizine hydrochloride and pseudoephedrine hydrochloride tablet, film
coated, extended release
Aurohealth LLC**

Drug Facts

Active ingredients (in each extended release tablet)

Cetirizine HCl USP 5 mg
Pseudoephedrine HCl USP 120 mg

Purpose

Antihistamine
Nasal decongestant

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
 - nasal congestion
- reduces swelling of nasal passages
- temporarily relieves sinus congestion and pressure
- temporarily restores freer breathing through the nose

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.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- heart disease

- thyroid disease
- diabetes
- glaucoma
- high blood pressure
- trouble urinating due to an enlarged prostate gland
- 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

- **do not use more than directed**
- 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.
- you get nervous, dizzy, or sleepless
- symptoms do not improve within 7 days or are accompanied by fever

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

- do not break or chew tablet; swallow tablet whole

adults and children 12 years and over	take 1 tablet every 12 hours; do not take more than 2 tablets in 24 hours.
adults 65 years and over	ask a doctor
children under 12 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)
- **do not use if carton is opened or if individual blister units are torn or broken**

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, ferric oxide, hypromellose, magnesium stearate, microcrystalline cellulose.

Questions or comments?

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

(Monday - Friday 8:30 AM to 5:00 PM EST)

Distributed by: **AUROHEALTH LLC**

279 Princeton-Hightstown Road
East Windsor, NJ 08520

Made in India

Code: AP/DRUGS/04/2016

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL -5 mg/120 mg (12 x 2) Blister Carton

AUROHEALTH

NDC 58602-703-09

***Compare to the active ingredients of Zyrtec-D®**

Original Prescription Strength

**Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablets, USP
5 mg/ 120 mg**

Antihistamine/Nasal Decongestant

Indoor & Outdoor Allergies

ALLERGY + SINUS

NASAL CONGESTION + SINUS PRESSURE

12 Hour relief of

Sneezing

Runny Nose

Itchy, Watery Eyes

Itchy Throat or Nose

Actual Size

**24
EXTENDED-RELEASE TABLETS**

Drug Facts (continued)

Ask a doctor before use if you have ■ heart disease ■ thyroid disease ■ diabetes ■ glaucoma ■ high blood pressure ■ trouble urinating due to an enlarged prostate gland ■ 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 ■ do not use more than directed ■ 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. ■ you get nervous, dizzy, or sleepless ■ symptoms do not improve within 7 days or are accompanied by fever

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. (1-800-222-1232)

Directions

■ do not break or chew tablet; swallow tablet whole

adults and children 12 years and over	take 1 tablet every 12 hours; do not take more than 2 tablets in 24 hours.
adults 65 years and over	ask a doctor
children under 12 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)
 ■ do not use if carton is opened or if individual blister units are torn or broken

Inactive ingredients
 colloidal silicon dioxide, croscarmellose sodium, ferric oxide, hypromellose, magnesium stearate, microcrystalline cellulose.

Drug Facts (continued)

Questions or comments? call 1-866-274-4122 (Monday – Friday 8:30 AM to 5:00 PM EST)

* This product is not manufactured or distributed by McNeil Consumer Healthcare, division of McNeil-PPC, Inc., distributor of Zyrtec-D®

Distributed by: AUROHEALTH LLC
 299 Pinetown-Hightstown Road
 East Windsor, NJ 08820
 Made in India



AUROHEALTH NDC 58602-703-09

Original Prescription Strength * Compare to the active ingredients of Zyrtec-D®

Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablets, USP Indoor & Outdoor Allergies

5 mg/120 mg Antihistamine/Nasal Decongestant

ALLERGY + SINUS

NASAL CONGESTION + SINUS PRESSURE

12 Hour relief of Sneezing

Runny Nose Itchy, Watery Eyes Itchy Throat or Nose

Actual Size **24** EXTENDED-RELEASE TABLETS

Drug Facts Important: Read all product information before using. Keep this box for important information.

Active Ingredients (In each extended release tablet)	Purpose
Cetirizine HCl USP 5 mg	Antihistamine
Pseudoephedrine HCl USP 120 mg	Nasal decongestant

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- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ runny nose ■ sneezing
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CETIRIZINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE
 cetirizine hydrochloride and pseudoephedrine hydrochloride tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-703
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
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics

Color	YELLOW (Pale Yellow to Yellow)	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	K15
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-703-76	4 in 1 CARTON	03/08/2023	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:58602-703-75	2 in 1 CARTON	03/08/2023	
2		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:58602-703-53	12 in 1 CARTON	03/08/2023	
3		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:58602-703-09	12 in 1 CARTON	03/08/2023	
4		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA212409	03/08/2023	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650918514	ANALYSIS(58602-703) , MANUFACTURE(58602-703)

Revised: 11/2024

Aurohealth LLC