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
Allergy & Sinus
INDOOR & OUTDOOR
ALLERGIES
12 HOUR RELIEF

NASAL CONGESTION & SINUS PRESSURE

- ***Sneezing***
- ***Runny Nose***
- ***Itchy, Watery Eyes***
- ***Itchy Nose or Throat***

(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. (1-800-222-1222)

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Drug Facts (continued)

Questions or comments? call 1-855-274-4122 (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
279 Princeton-Hightstown Road
East Windsor, NJ 08520
Made in India
Code: AP/DRUGS/104/2016

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Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablets, USP
5 mg/120 mg
Antihistamine/Nasal Decongestant
Allergy & Sinus
INDOOR & OUTDOOR ALLERGIES
24
EXTENDED-RELEASE TABLETS

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

5 mg/120 mg

Antihistamine/Nasal Decongestant

Allergy & Sinus

INDOOR & OUTDOOR ALLERGIES

12 HOUR RELIEF

NASAL CONGESTION & SINUS PRESSURE

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Nose or Throat

(Actual Size) 24

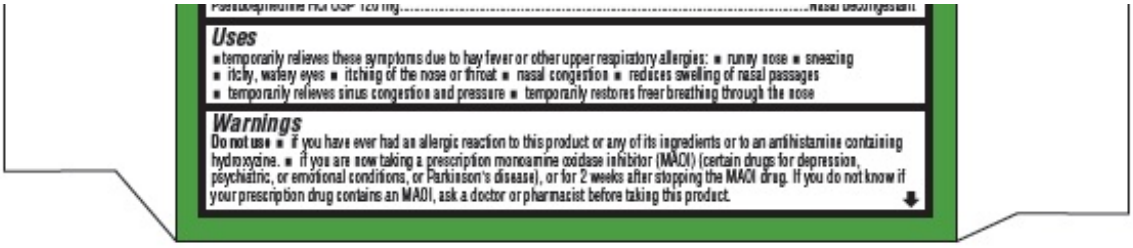
EXTENDED-RELEASE TABLETS

Lot:
Exp.:

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



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)	
CROSCARMELLOSE 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: 3/2023 Aurohealth LLC