ALLERGY RELIEF D- cetirizine hydrochloride, pseudoephedrine hydrochloride tablet, film coated, extended release Publix Super Markets Inc

Publix Super Markets, Inc. Allergy Relief D Drug Facts

Active ingredients (in each extended release tablet)

Cetirizine HCl 5 mg

Pseudoephedrine HCl 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 pregnancy 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 68° to 77°F (20° to 25°C)
- do not use if blister unit is broken or torn
- see side panel for lot number and expiration date
- meets USP Dissolution Test 2

Inactive ingredients

colloidal silicon dioxide, hypromellose, lactose monohydrate, low-substituted hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide

Package/Label Principal Display Panel

INDOOR & OUTDOOR ALLERGIES

allergy relief D

CETIRIZINE HYDROCHLORIDE & PSEUDOEPHEDRINE HYDROCHLORIDE

EXTENDED-RELEASE TABLETS, 5 mg/120mg

ANTIHISTAMINE/NASAL DECONGESTANT

ALLERGY & CONGESTION

12-hour relief of:

Sneezing - Itchy, watery eyes - Runny nose

Itchy throat or nose - Sinus pressure - Nasal congestion

ACTUAL SIZE

12 EXTENDED-RELEASE TABLETS

Compare to Zyrtec®

active ingredients



IZINE HYDROCHLORIDE & PSEUDOEPHEDRINE HYDROCHLORIDE EXTENDED-RELEASE TABLETS, 5 mg/120 mg
ANTIHISTAMINE/NASAL DECONGESTANT

ALLERGY & CONGESTION



NDC 56062-147-53

INDOOR & OUTDOOR ALLERGIES

allergyrelief**D**

CETIRIZINE HYDROCHLORIDE & PSEUDOEPHEDRINE HYDROCHLORIDE EXTENDED-RELEASE TABLETS, 5 mg/120 mg ANTIHISTAMINE/NASAL DECONGESTANT

ALLERGY & CONGESTION

Purp ose

12-hour relief of:

- · Sneezing · Itchy, watery eyes · Runny nose
- Itchy throat or nose
 Sinus pressure
 Nasal congestion





ACTUAL SIZE

*Compare to Zyrtec-D® active ingredients

Drug Facts

Active ingredients

(in each extended release tablet)

Cetiriz ine HCl 5 mg......Antihi stamine Pseudoephedrine HCl 1 20 mg......Nasal decongestant

14753 63

- 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
- red uces swelling of nas al pass ages
- temporarily relievess inuscongestion and pressure temporarily restores freer breathing through the nose

Warni ngs

Donotuse

- if you have ever had an allergic reaction to this product or any of its ingredients or to an antihi stamine containing hydroxyzin e.
- you are now taking a prescription monoamine oxidas e inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 week safters topping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharm a cist before taking this product.

Ask adoctor before use if you have

- heart disease thy roid disease diabetes
 glaucoma high blood pressure
 trouble urinating due to an enlarged pros ate gland
- liverorkidn eydisease. Yourdoctorshould determine if you need a different dose

Drug Facts (continued)

Aska doctororphamna cistbefore use if you are taking tranquili zersor s edatives.

- When using this product do not use more than directed drowsiness may occur avoid alcoholicdrinks alcohol, sedatives, and tranquilizers may increase drows iness ■ be careful when driving a motor vehicle or operating machinery

Stop use and ask adoctor if

- an allergic reaction to this product occurs. Seek medical help
- right away. you get nervous, di zzy, ors leepless
- symptoms donot improve within 7 days or are accompanied

If preg nant 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. (1-8 00-222-1 222)

Direct ions

■ do not break or chew tablet swallow tablet whole		
adults and children 12 years and over	take 1 tablet every 12 hours;d onot take more than 2 tablets in 24 hours.	
adults 65 years and over	as ka doctor	
children under 12 yearsof age	ask a doctor	
consumers with liver or kidney disease	aska doctor	

DISTRIBUTED BY PUBLIX SUPER MARKETS, INC., 3300 PUBLIX CORPORATE PARKWAY, LAKELAND, FL 33811 publix.com 1-888-267-3037 PUBLIX GUARANTEE: COMPLETE SATISFACTION OR YOUR MONEY BACK

ublix.

Drug Facts (continued)

Other information

- store between 68° to 77° F (20° to 25° C)
- don ot u se if b lister unit is b no ken ort orn
 see side panel for lot number and expiration date meets USP Dissolut on Test 2

Inactive in gred ients colloidal silicon dioxide, hypromellose, lactose monohydrate, low-subs futed hy droxy propyl cellul ose, magnesium stearate, microcry stalline cellulose, polyethy lene glycol, poly vin yl alcohol, talc, titanium dioxi de *This product is not manufactured or distributed by the owner of the registered trademark Zyrtec-D®,



ALLERGY RELIEF D

cetirizine hydrochloride, pseudoephedrine hydrochloride tablet, film coated, extended release

Dun dunck	1 4	:
Product	Intorm	ation

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56062-147
--------------	----------------	--------------------	---------------

Route of Administration ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
CETIRIZINE HYDROCHLORIDE (UNII: 640047KTOA) (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)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 2165RE0K14)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	WHITE	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	L147
Contains			

Packaging				
Item Code	Package Description	Marketing Start Date	Marketing End Date	
NDC:56062-147- 53	12 in 1 CARTON	02/12/2021		
	1 in 1 BLISTER PACK; Type 0: Not a Combination Product			
NDC:56062-147- 62	24 in 1 CARTON	02/16/2021		
	1 in 1 BLISTER PACK; Type 0: Not a Combination Product			
	Item Code NDC:56062-147- 53	NDC:56062-147- 53 12 in 1 CARTON 1 in 1 BLISTER PACK; Type 0: Not a Combination Product NDC:56062-147- 62 24 in 1 CARTON 1 in 1 BLISTER PACK; Type 0: Not a Combination	Item CodePackage DescriptionMarketing Start DateNDC:56062-147-5312 in 1 CARTON02/12/20211 in 1 BLISTER PACK; Type 0: Not a Combination Product02/16/2021NDC:56062-147-6224 in 1 CARTON02/16/20211 in 1 BLISTER PACK; Type 0: Not a Combination	

Marketing I	nformation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210719	02/12/2020	

Labeler - Publix Super Markets Inc (006922009)

Revised: 2/2021 Publix Super Markets Inc