ALLERGY RELIEF D- cetirizine hcl, pseudoephedrine hcl tablet, 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 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.

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)

Inactive ingredients

colloidal silicon dioxide, hydroxypropyl cellulose, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, talc, yellow iron oxide

Principal Display Panel

INDOOR & OUTDOOR ALLERGIES

AllergyreliefD

CETIRIZINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE

EXTENDED RELEASE TABLETS, 5 mg/120 mg

ANTIHISTAMINE/NASAL DECONGESTANT

ALLERGY & CONGESTION

12 hour relief of:

sneezing - itchy, watery eyes - runny nose

itchy throat or nose - nasal congestion - sinus pressure

ACTUAL SIZE

12 EXTENDED RELEASE TABLETS

Compare to the Active Ingredients in Zyrtec-D®



Drug Facts Drug Facts (continued) Active ingredients fever or other upper respiratory allergies: Purpose ■ runny nose ■ sneezing ■ itchy, watery eyes (in each extended release tablet) ■ itching of the nose or throat ■ nasal congestion Cetirizine HCI 5 mg......Antihistamine Pseudoephedrine HCI 120 mg......Nasal Decongestant ■ reduces swelling of nasal passages ■ temporarily relieves sinus congestion and pressure ■ temporarily restores freer breathing through ■ temporarily relieves these symptoms due to hay Drug Facts (continued) Drug Facts (continued) Warnings ■ you get nervous, dizzy, or sleepless Do not use ■ symptoms do not improve within 7 days or are if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine accompanied by fever If pregnant or breast-feeding: containing hydroxyzine. if you are nowtaking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or ■ if breast-feeding; not recommended ■ if pregnant: ask a health professional before use. Keep out of reach of children. In case of overdose, get Parkinson's disease), or for 2 weeks after stopping the medical help or contacta Poison Control Center right away. MAOI drug. If you do not know if your prescription Directions 1 4 1 drug contains an MAOI, ask a doctor or pharmacist ■ do not break or chew tablet; swallow tablet whole before taking this product. adults and children take 1 tablet every 12 hours: Ask a doctor before use if you have 12 years and over do not take more than 2 tablets ■ heart disease ■ thyroid disease ■ diabetes ■ high blood pressure in 24 hours. ■ glaucoma ■ trouble urinating due to an enlarged prostate gland ■ Iver or kidney dis ease. Your doctor should determine adults 65 years aska doctor and over if you need a different dose. children under ask a doctor Ask a doctor or pharmacist before use if you are taking 12 years of age tranquilizers or sedatives. consumers with liver When using this product aska doctor

or kidney disease

Other information

Inactive ingredients

■ store between 20° to 25°C (68° to 77°F)

colloid al silicon dioxid e, hydroxypropyl cellulose,

microcrystalline cellulose, talc, yellow iron oxide

hypromellose, lactose mon ohy drate, magnesium stearate,

ALLERGY RELIEF D

cetirizine hcl, pseudoephedrine hcl tablet, extended release

■ do not use more than directed

Stop use and ask a doctor if

Seek medical help right away.

drowsiness

machinery

■ drowsiness may occur ■ avoid alcoholic drinks ■ alcohol, sedatives, and tranquilizers may increase

■ be careful when driving a motor vehicle or operating

■ an allergic reaction to this product occurs.

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56062-176
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CETIRIZINE HYDRO CHLO RIDE (UNII: 640047KTOA) (CETIRIZINE - UNII: YO7261ME24)	CETIRIZINE HYDROCHLORIDE	5 mg	
PSEUDO EPHEDRINE HYDRO CHLO RIDE (UNII: 6 V9 V2RYJ8 N) (PSEUDO EPHEDRINE - UNII:7CUC9 DDI9 F)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg	

Inactive Ingredients		
Ingredient Name	Strength	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
HYPROMELLOSES (UNII: 3NXW29 V3WO)		
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)		
MAGNESIUM STEARATE (UNII: 70097M6130)		
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
TALC (UNII: 7SEV7J4R1U)		
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)		

Product Characteristics			
Color	WHITE (one side white one side light yellow)	Score	no score
Shape	ROUND	Size	12mm
Flavor		Imprint Code	5029;5;120
Contains			

1	Packaging			
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062-176-53	2 in 1 CARTON	03/11/2010	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:56062-176-62	4 in 1 CARTON	03/11/2010	
2		6 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	ANDA077170	03/11/2010	

Labeler - Publix Super Markets Inc (006922009)

Revised: 12/2018 Publix Super Markets Inc