

**ALLERGY RELIEF D- loratadine, pseudoephedrine sulfate tablet, film coated, extended release  
Publix Super Markets Inc**

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**Publix Super Markets, Inc. Allergy Relief D Drug Facts**

**Active ingredients (in each tablet)**

Loratadine 5 mg

Pseudoephedrine sulfate 120 mg

**Purpose**

Antihistamine

Nasal decongestant

**Uses**

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
- sneezing
- itchy, watery eyes
- runny nose
- itching of the nose or throat
- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- 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
- 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
- high blood pressure
- diabetes
- trouble urinating due to an enlarged prostate gland
- liver or kidney disease. Your doctor should determine if you need a different dose.

**When using this product do not take more than directed.**

Taking more than directed may cause drowsiness.

**Stop use and ask a doctor if**

- an allergic reaction to this product occurs. Seek medical help right away.
- symptoms do not improve within 7 days or are accompanied by a fever
- nervousness, dizziness or sleeplessness occurs

**If pregnant or breast-feeding,**

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 divide, crush, chew or dissolve the tablet

adults and children 12 years and over	1 tablet every 12 hours; not more than 2 tablets in 24 hours
children under 12 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

**Other information**

- **each tablet contains:** calcium 25 mg
- do not use if blister unit is broken or torn
- store between 68° to 77°F (20° to 25°C)
- keep in a dry place

**Inactive ingredients**

croscarmellose sodium, dibasic calcium phosphate, hypromellose, lactose monohydrate, magnesium stearate, pharmaceutical ink, povidone, titanium dioxide

**Package/Label Principal Display Panel**

12-HOUR – NON-DROWSY\*

allergy relief D

PSEUDOEPHEDRINE SULFATE 120 mg/LORATADINE 5 mg

EXTENDED RELEASE TABLETS

NASAL DECONGESTANT/ANTI-HISTAMINE

ALLERGY & CONGESTION

Relief of:

Nasal and sinus congestion due to colds or allergies

Sneezing - Runny nose - Itchy, watery eyes

Itchy throat or nose due to allergies

INDOOR AND OUTDOOR ALLERGIES

10 EXTENDED RELEASE TABLETS

ACTUAL SIZE

\*When taken as directed. See Drug Facts Panel.

Compare to Claritin-D<sup>®</sup> 12 hour Extended Release Tablets active ingredients



12-HOUR • NON-DROWSY\*

# allergyreliefD

PSEUDOEPHEDRINE SULFATE 120 mg/  
LORATADINE 5 mg EXTENDED RELEASE TABLETS

NASAL DECONGESTANT/ANTIHISTAMINE  
ALLERGY & CONGESTION

\*When taken as directed, See Drug Facts panel.



NDC 56062-555-46

12-HOUR • NON-DROWSY\*

# allergyreliefD

PSEUDOEPHEDRINE SULFATE 120 mg/  
LORATADINE 5 mg EXTENDED RELEASE TABLETS

NASAL DECONGESTANT/ANTIHISTAMINE  
ALLERGY & CONGESTION

### Relief of:

- Nasal and sinus congestion due to colds or allergies
- Sneezing • Runny nose • Itchy, watery eyes
- Itchy throat or nose due to allergies

INDOOR AND OUTDOOR ALLERGIES

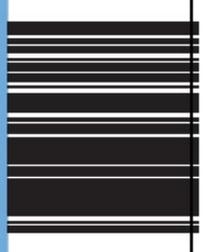
**10** EXTENDED RELEASE  
TABLETS



ACTUAL SIZE

\*When taken as directed. See Drug Facts panel.

Compare to Claritin-D® 12 Hour Extended  
Release Tablets active ingredients\*\*



7U046 63 C3

### Drug Facts

Active ingredients (in each tablet)	Purpose
Loratadine 5 mg.....	Antihistamine
Pseudoephedrine sulfate 120 mg.....	Nasal decongestant

### Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
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### Warnings

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#### Ask a doctor before use if you have

- heart disease
- thyroid disease
- high blood pressure
- diabetes
- trouble urinating due to an enlarged prostate gland
- liver or kidney disease. Your doctor should determine if you need a different dose.

### Drug Facts (continued)

When using this product do not take more than directed. Taking more than directed may cause drowsiness.

#### Stop use and ask a doctor if

- an allergic reaction to this product occurs. Seek medical help right away.
- symptoms do not improve within 7 days or are accompanied by a fever
- nervousness, dizziness or sleepiness occurs

If pregnant or breast-feeding, 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 divide, crush, chew or dissolve the tablet
- adults and children 12 years and over: 1 tablet every 12 hours; not more than 2 tablets in 24 hours
- children under 12 years of age: ask a doctor
- consumers with liver or kidney disease: ask a doctor

#### Other information

- each tablet contains calcium 25 mg
- do not use if blister unit is broken or torn
- store between 68° to 77° F (20° to 25° C)
- keep in a dry place

#### Inactive ingredients

cross carmellose sodium, dibasic calcium phosphate, hypromellose, lactose monohydrate, magnesium stearate, pharmaceutical ink, povidone, titanium dioxide

\*\*This product is not manufactured or distributed by Bayer HealthCare LLC, distributor of Claritin-D® 12 Hour Extended Release Tablets.

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# ALLERGY RELIEF D

loratadine, pseudoephedrine sulfate tablet, film coated, extended release

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56062-555
Route of Administration	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LORATADINE (UNII: 7AJ03BO7QN) (LORATADINE - UNII:7AJ03BO7QN)	LORATADINE	5 mg
PSEUDOEPHEDRINE SULFATE (UNII: Y9DL7QPE6B) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE SULFATE	120 mg

## Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

Color	WHITE (to off-white)	Score	no score
Shape	ROUND	Size	12mm
Flavor		Imprint Code	7U0
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062-555-46	10 in 1 CARTON	04/23/2018	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:56062-555-60	20 in 1 CARTON	04/23/2018	
2		1 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	ANDA076050	04/23/2018	

