

**ALLERGY AND CONGESTION RELIEF- loratadine, pseudoephedrine sulfate tablet, film coated, extended release**

**Kroger Company**

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**Kroger Co. Allergy & Congestion Relief 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 20° to 25°C (68° to 77°F)
- keep in a dry place

**Inactive ingredients**

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

**Questions or comments?**

**1-800-632-6900**

**Package/Label Principal Display Panel**

COMPARE TO the active ingredients of CLARITIN-D® 12 HOUR

See bottom panel

OUR PHARMACIST RECOMMENDED

Non-Drowsy\*

Allergy & Congestion Relief

actual size

RELIEF OF:

Nasal & Sinus Congestion Due to Colds & Allergies

Sneezing; Runny Nose

Itchy, Watery Eyes

Itchy Throat or Nose Due to Allergies

Pseudoephedrine Sulfate 120 mg/Nasal Decongestant

Loratadine 5 mg/Antihistamine

Extended-Release Tablets

Indoor & Outdoor Allergies

12 HOUR

30 EXTENDED-RELEASE TABLETS

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



# Non-Drowsy\* Allergy & Congestion Relief

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Pseudoephedrine Sulfate 120 mg/  
Nasal Decongestant  
Loratadine 5 mg/Antihistamine  
Extended-Release Tablets

**12**  
HOUR

COMPARE TO the active ingredients of CLARITIN-D® 12 HOUR \*\*See bottom panel

NDC 30142-786-65



# Non-Drowsy\* Allergy & Congestion Relief

Pseudoephedrine Sulfate 120 mg/  
Nasal Decongestant  
Loratadine 5 mg/ Antihistamine  
Extended-Release Tablets

Indoor & Outdoor Allergies

**12**  
HOUR

**30** EXTENDED-RELEASE  
TABLETS

actual  
size

**RELIEF OF:**  
Nasal & Sinus  
Congestion Due to  
Colds or Allergies

Sneezing; Runny Nose  
Itchy, Watery Eyes  
Itchy Throat or Nose  
Due to Allergies

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7U065 45 C3

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### Drug Facts (continued)

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- do not use if blister unit is broken or torn
- store between 20° to 25° C (68° to 77° F)
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**Inactive ingredients** croscarmellose sodium, dibasic calcium phosphate, hypromellose, lactose monohydrate, magnesium stearate, pharmaceutical ink, povidone, titanium dioxide

### Drug Facts (continued)

Questions or comments? 1-800-632-6900

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

DISTRIBUTED BY THE KROGER CO.  
CINCINNATI, OHIO 45202  
QUALITY GUARANTEE  
800-632-6900 | www.kroger.com

GLUTEN FREE



PLEASE  
RECYCLE



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# ALLERGY AND CONGESTION RELIEF

loratadine, pseudoephedrine sulfate tablet, film coated, extended release

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30142-786
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)	
ANHYDRO US 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:30142-786-65	30 in 1 CARTON	05/18/2018	
1		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	05/18/2018	

Labeler - Kroger Company (006999528)

