

**LEADER ALLERGY RELIEF D12- loratadine, pseudoephedrine sulfate tablet,
film coated, extended release
Cardinal Health 110, LLC. dba Leader**

Cardinal Health Allergy Relief D-12 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?

1-800-719-9260

Package/Label Principal Display Panel

Non-Drowsy* | 12 Hour

Allergy Relief D-12

Pseudoephedrine Sulfate, 120 mg | Loratadine, 5 mg

Extended-Release Tablets

Nasal Decongestant | Antihistamine

Allergy and Congestion

Indoor and Outdoor Allergies

Relief of: - Nasal and Sinus Congestion Due to Colds or Allergies

Sneezing - Runny Nose - Itchy, Watery Eyes

Itchy Throat or Nose Due to Allergies

COMPARE TO CLARITIN-D® 12 HOUR EXTENDED RELEASE TABLETS active ingredients

*When Taken as Directed. See Drug Facts Panel.

10 EXTENDED RELEASE TABLETS

Actual Size

100% Money Back Guarantee



Drug Facts

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Drug Facts (continued)

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Drug Facts (continued)

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All LEADER™ Brand Products Have A 100% Money Back Guarantee

Return to place of purchase if not satisfied.

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Cardinal Health™

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DUBLIN, OHIO 43017
www.myleader.com 1-800-200-6335
Essential to Care™ since 1979

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

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LEADER ALLERGY RELIEF D12

loratadine, pseudoephedrine sulfate tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0504
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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	

HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
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:70000-0504-3	30 in 1 CARTON	01/09/2020	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:70000-0504-2	20 in 1 CARTON	01/09/2020	
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:70000-0504-1	10 in 1 CARTON	01/09/2020	
3		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	01/09/2020	

Labeler - Cardinal Health 110, LLC. dba Leader (063997360)

Revised: 6/2021

Cardinal Health 110, LLC. dba Leader