

LEADER ALLERGY RELIEF D-24- loratadine and pseudoephedrine sulfate tablet, film coated, extended release
Cardinal Health

Drug Facts

Active ingredients

Loratadine, USP 10 mg

Pseudoephedrine Sulfate, USP 240 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
- reduces swelling of nasal passages
- temporarily relieves sinus congestion and pressure
- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- 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 daily with a full glass of water; not more than 1 tablet in 24 hours
children under 12 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

Other Information

- **sodium: contains 10 mg/tablet** ■ **calcium: contains 25 mg/tablet**

■ TAMPER EVIDENT: DO NOT USE IF BLISTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING. (for blister cartons only)

- store between 20° C to 25° C (68° F to 77° F).
- protect from light and store in a dry place

Inactive Ingredients

calcium carbonate, colloidal silicon dioxide, hydroxypropyl cellulose, hypromellose, iron oxide black, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, propylene glycol, shellac glaze, sodium alginate, sodium citrate, talc and titanium dioxide

Questions

call **1-800-406-7984**

Package/Label Principal Display Panel

NDC 70000-0162-1

Original Prescription Strength

***Compare to the active ingredients of Claritin-D® 24 Hour**

NON-DROWSY*

Allergy Relief D-24

Loratadine, USP 10 mg/Antihistamine

Pseudoephedrine Sulfate, USP 240 mg/Nasal Decongestant

Indoor & Outdoor Allergies

Allergy & Congestion

Relief of:

Nasal & Sinus Congestion Due to Colds or Allergies

Sneezing

Runny Nose

Itchy, Watery Eyes

Itchy Throat or Nose Due to Allergies

Allergy & Congestion

10 Extended-Release Tablets

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

Keep the carton. It contains important information.

see end panel for expiration date.

Drug Facts (continued)

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, high blood pressure, thyroid disease, diabetes, trouble urinating due to an enlarged prostate gland 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.

Warnings

- redness, swelling, or nasal passages
- temporarily relieves sinus congestion and pressure
- temporarily relieves nasal congestion due to the common cold, hay fever, or other upper respiratory allergies
- temporarily relieves fever or aches and pains

Drug Facts (continued)

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 breastfeeding, 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

adults and children 12 years and over: 1 tablet daily with a full glass of water; not more than 1 tablet in 24 hours

children under 12 years of age: ask a doctor

consumers with liver or kidney disease: ask a doctor

Other Information

- sodium: contains 10 mg/kabul
- calcium: contains 25 mg/tablet
- TAPE REMOVAL: DO NOT USE IF BLISTERS UNITS ARE TOP, BROKEN OR SHOW ANY SIGNS OF TAMPERING.
- store between 20° C to 25° C (68° F to 77° F).
- protect from light and store in a dry place.

Drug Facts

Active Ingredients (in each tablet)

Loratadine, USP 10 mg; Pseudoephedrine sulfate, USP 240 mg. Nasal Decongestant

Purpose

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.

Non-Drowsy*

Allergy Relief D-24

Loratadine, USP 10 mg | Antihistamine
Pseudoephedrine Sulfate, USP 240 mg | Nasal Decongestant

**Indoor & Outdoor Allergies
Allergy & Congestion**

24 Hour Relief of:
Nasal & Sinus Congestion Due to Colds or Allergies
Sneezing; Runny Nose; Itchy, Watery Eyes;
Itchy Throat or Nose Due to Allergies

COMPARE TO CLARITIN-D® 24 HOUR active ingredients*

100% Money Back Guarantee

10 EXTENDED-RELEASE TABLETS

*When taken as directed. See Drug Facts Panel.

Keep the carton. It contains important information.
See end panel for expiration date.

Questions? call 1-800-406-7984

Inactive Ingredients: calcium carbonate, colloidal silicon dioxide, hydroxypropylcellulose, hypromellose, iron oxide black, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polydioxane, pregelatinized starch, polyethylene glycol, silica gel, sodium alginate, sodium citrate, talc and titanium dioxide.

This product is not manufactured or distributed by BAYER HEALTHCARE LLC, owner of the registered trademark CLARITIN-D® 24 HOUR.

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CardinalHealth™

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 Expiration Date:
 Batch No.

Non Varnish Area

Principal Display Panel

NDC 70000-0162-2

Original Prescription Strength

***Compare to the active ingredients of Claritin-D® 24 Hour**

NON-DROWSY**

Allergy Relief D-24

Loratadine, USP 10 mg/Antihistamine

Pseudoephedrine Sulfate, USP 240 mg/Nasal Decongestant

Indoor & Outdoor Allergies

Allergy & Congestion

Relief of:

Nasal & Sinus Congestion Due to Colds or Allergies

Sneezing

Runny Nose

Itchy, Watery Eyes

Itchy Throat or Nose Due to Allergies

Allergy & Congestion

15 Extended-Release Tablets

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

Keep the carton. It contains important information.

see end panel for expiration date.

LEADER[™]

Non-Drowsy*

Allergy Relief D-24

Loratadine, USP 10 mg | Antihistamine
Pseudoephedrine Sulfate, USP 240 mg | Nasal Decongestant

15 EXTENDED-RELEASE TABLETS

LEADER[™]

NDC 70000-0162-2

Non-Drowsy*

Allergy Relief D-24

Loratadine, USP 10 mg | Antihistamine
Pseudoephedrine Sulfate, USP 240 mg | Nasal Decongestant

Indoor & Outdoor Allergies
Allergy & Congestion

24 Hour Relief of:

Nasal & Sinus Congestion Due to Colds or Allergies
Sneezing; Runny Nose; Itchy, Watery Eyes;
Itchy Throat or Nose Due to Allergies

COMPARE TO CLARITIN-D[®]
24 HOUR active ingredients[†]

100% Money Back Guarantee

15 EXTENDED-RELEASE TABLETS

*When taken as directed. See Drug Facts Panel.

†This product is not manufactured or distributed by BAYER HEALTHCARE LLC., owner of the registered trademark CLARITIN-D[®] 24 HOUR.



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Essential to Care - since 1919



Non Varnish Area

Batch No.

Expiration Date

Keep the carton. It contains important information. See end panel for expiration date.
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Questions? Call 1-800-45-7984

Inactive ingredients calcium carbonate, colloid silicon dioxide, hydroxypropyl cellulose, hydroxypropyl methylcellulose, hypromellose, iron oxide black, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polydioxane, pregelatinized starch, polyethylene glycol, shellac, silica, sodium alginat, sodium citrate, stearic acid, and titanium dioxide

- product from light and store in a dry place
- store between 20° C to 25° C (68° F to 77° F).
- TAMPER EVIDENT: DO NOT USE IF PUSTERS UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING.
- contains 25 mg of pseudoephedrine sulfate per tablet
- sodium citrate 10 mg per tablet

Other Information

Drug Facts (continued)

Warnings
Do not use if you have ever had an allergic reaction to this product or any of its ingredients. You are now taking a prescription medication (or have taken one in the past) that may interact with this product (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or 2 weeks after stopping the MAOI drug. If you do not know if you are taking a MAOI drug, ask your doctor or pharmacist before taking this product.

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
■ redness or swelling of the nasal passages
Temporarily relieves sinus congestion and pressure in the nostrils and sinuses.
Temporarily relieves nasal congestion due to the common cold, hay fever, or other upper respiratory allergies.
Temporarily restores free breathing through the nose.

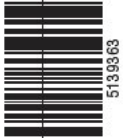
Active Ingredients
Loratadine, USP 10 mg..... Antihistamine
Pseudoephedrine sulfate, USP 240 mg..... Nasal decongestant
(in each tablet)

Purpose
Ask a doctor before use if you have:
■ thyroid disease
■ heart disease
■ diabetes
■ 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.

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
■ frequent 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 chew, crush, chew or dissolve the tablet
■ adults and children 12 years and over: 1 tablet daily with a full glass of water, not more than 1 tablet in 24 hours
■ children under 12 years of age: ask a doctor
■ ask a doctor if you are pregnant, nursing, or have a kidney disease

Drug Facts (continued)



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LEADER ALLERGY RELIEF D-24

loratadine and pseudoephedrine sulfate tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0162
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LORATADINE (UNII: 7AJ03BO7QN) (LORATADINE - UNII:7AJ03BO7QN)	LORATADINE	10 mg
PSEUDOEPHEDRINE SULFATE (UNII: Y9DL7QPE6B) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE SULFATE	240 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
SHELLAC (UNII: 46N107B710)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	RX724
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0162-1	10 in 1 BLISTER PACK; Type 0: Not a Combination Product	01/15/2020	
	NDC:70000-	15 in 1 BLISTER PACK; Type 0: Not a Combination Product		

2	NDC: 70000-0162-2	15 in 1 BLISTER PACK; Type U: Not a Combination Product	01/15/2020
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076557	02/15/2017	

Labeler - Cardinal Health (063997360)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		051565745	MANUFACTURE(70000-0162)

Revised: 3/2022

Cardinal Health