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

DRUG FACTS

ACTIVE INGREDIENTS (IN EACH TABLET)

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 IMPRINTED SEAL IS BROKEN OR MISSING FROM BOTTLE.** ***(for bottle cartons/labels only)***
- **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**

KEEP THE CARTON. IT CONTAINS IMPORTANT INFORMATION. SEE END PANEL FOR EXPIRATION DATE.

DISTRIBUTED BY CARDINAL HEALTH

DUBLIN, OHIO 4301

www.myleader.com 1-800-200-6313

PACKAGE LABEL. PRINCIPAL DISPLAY PANEL

NDC 37205-348-52

LEADER®

†Compare to Claritin-D® 24 Hour active ingredients

24 Hour

Non-Drowsy*

ORIGINAL PRESCRIPTION STRENGTH

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 CongestionDue to Colds or Allergies

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

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

10 EXTENDED-RELEASE TABLETS

†The product is not manufactured or distributed by Schering-Plough Healthcare Products, Inc. CLARITIN-D® 24 HOUR is a registered trademark of Schering Corporation.

Drug Facts (continued)

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

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

Batch No.

Expiration Date:

COATING FREE AREA

10 EXTENDED-RELEASE TABLETS

SATISFACTION GUARANTEED

*When taken as directed. See Drug Facts Panel.

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

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

Allergy & Congestion

Indoor & Outdoor Allergies

Allergy Relief D-24

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

ORIGINAL PRESCRIPTION STRENGTH

Non-Drowsy*

24 Hour

Compare to Claritin-D® 24 Hour active ingredients†

LEADER®

NDC 37205-348-62

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DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43017
CIN 3474921
www.myleadec.com 1-800-200-6313

All Leader® Brand products are 100% satisfaction guaranteed or return to place of purchase for a full refund.

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Drug Facts

Active ingredients (in each tablet)	Purpose
Loratadine, USP 10 mg	Antihistamine
Pseudoephedrine sulfate, USP 240 mg	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

Drug Facts (continued)

■ reduces swelling of nasal passages ■ temporarily relieves sinus congestion and pressure
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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
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■ nervousness, dizziness or sleeplessness occurs

If pregnant or breast-feeding, ask a health professional before use.
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COATING FREE AREA

5079422

COATING FREE AREA

5079422

COATING FREE AREA

326356

10's blister carton

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:37205-348
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN)	LORATADINE	10 mg
PSEUDOEPHEDRINE SULFATE (UNII: Y9DL7QPE6B) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE	240 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CALCIUM CARBONATE (UNII: H0G9379FGK)	
COLLOIDAL SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	

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:37205-348-52	10 in 1 BLISTER PACK		
2	NDC:37205-348-88	15 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076557	11/17/2004	

Labeler - Cardinal Health (097537435)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		051565745	manufacture

Revised: 3/2012 Cardinal Health