LORATADINE AND PSEUDOEPHEDRINE SULFATE- loratadine and pseudoephedrine sulfate tablet, film coated, extended release
The Kroger Company

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 BLISTER UNITS ARE TORN, 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

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 OR COMMENTS?

1-800-632-6900

PRINCIPAL DISPLAY PANEL - 240 mg/10 mg Tablet Blister Pack Carton

COMPARE TO the active ingredients of CLARITIN-D® 24 HOUR
**See side panel

Kroger®

FROM OUR FAMILY
TO YOURS

ORIGINAL PRESCRIPTION STRENGTH
NON-DROWSY*

NDC 30142-724-69

Allergy &
Congestion Relief
Loratadine and Pseudoephedrine Sulfate

24
HOUR

EXTENDED-RELEASE TABLETS

*When taken
as directed.
See Drug
Facts Panel.

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

Indoor & Outdoor
Allergies

Relief of:

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

Our Pharmacists
Recommend

10
EXTENDED-RELEASE
TABLETS

actual size

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**See side panel

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NDC 30142-724-69

Allergy & Congestion Relief

Loratadine and Pseudoephedrine Sulfate

24 HOUR

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Loratadine, USP 10 mg, Antihistamine

FROM OUR FAMILY TO YOURS

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Our Pharmacists Recommend

actual size

10 EXTENDED-RELEASE TABLETS

Expiration Date:

Batch No.

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

Questions or comments? 1-800-632-6900

pregelatinized starch, propylene glycol, shellac glaze, sodium alginate, sodium citrate, talc and titanium dioxide

DISTRIBUTED BY THE KROGER CO., CINCINNATI, OHIO 45202

QUALITY GUARANTEE

www.kroger.com

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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
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Drug Facts (continued)

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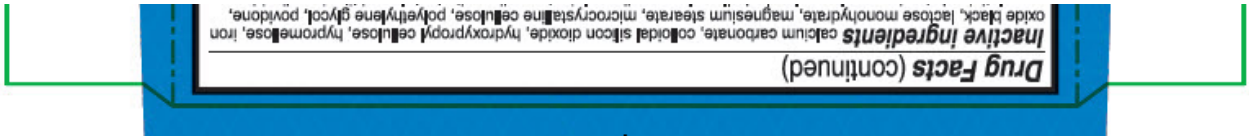

LORATADINE AND PSEUDOEPHEDRINE SULFATE

loratadine and pseudoephedrine sulfate tablet, film coated, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:30142-724
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 SULFATE	240 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CALCIUM CARBONATE (UNII: H0G9379FGK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	white (White to Off-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:30142-724-69	10 in 1 CARTON	11/17/2004	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:30142-724-15	15 in 1 CARTON	11/17/2004	
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	ANDA076557	11/17/2004	

Labeler - The Kroger Company (006999528)

Registrant - Sun Pharmaceutical Industries Inc. (146974886)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		051565745	manufacture(30142-724)

Revised: 12/2019 The Kroger Company