

LORATADINE AND PSEUDOEPHEDRINE SULFATE- loratadine and pseudoephedrine sulfate tablet, film coated, extended release
Chain Drug Consortium, LLC

Loratadine and Pseudoephedrine Sulfate

Drug Facts

<i>Active ingredients (in each tablet)</i>	<i>Purpose</i>
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
- 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?

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

Distributed By:
Pharmacy Value Alliance, LLC
407 East Lancaster Avenue,
Wayne, PA 19087

PRINCIPAL DISPLAY PANEL - 10 Tablet Blister Pack Carton

COMPARE TO THE ACTIVE
INGREDIENTS OF CLARITIN-D® 24 HOUR†

Original Prescription Strength
NON-DROWSY*

Premier
Value®

24 Hour Allergy Relief

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

ALLERGY RELIEF and
NASAL DECONGESTANT

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

10
Allergy & Congestion
Extended-Release Tablets

INDEPENDENTLY TESTED
SATISFACTION GUARANTEED

*When taken as directed. See Drug Facts Panel.

5131572



5131572



Drug Facts (continued)

■ temporarily restores nasal congestion and pressure
 ■ temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
 ■ temporarily restores free 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 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.

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Uses

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Purpose

Antihistamine
 Nasal decongestant

COMPARE TO THE ACTIVE INGREDIENTS OF CLARITIN-D® 24 HOUR* ORIGINAL PRESCRIPTION STRENGTH NON-DROWSY*

24 Hour Allergy Relief

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

ALLERGY RELIEF and NASAL DECONGESTANT

Relief of: **Indoor & Outdoor Allergies**

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

10 Allergy & Congestion Extended-Release Tablets

*When taken as directed. See Drug Facts Panel.

PREMIER VALUE

INDEPENDENTLY TESTED EXPIRATION GUARANTEED

† All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Claritin-D®. **Keep the carton. It contains important information. See end panel for expiration date.**

Expiration Date: _____
 Batch No. _____

Non Varnish Area

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

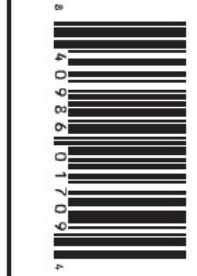
Questions? call 1-800-406-7984

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

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 Pharmacy ValueAlliance, LLC
 407 East Lancaster Avenue,
 Wayne, PA 19087

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For any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.



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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:68016-724
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:7CUC9DD19F)	PSEUDOEPHEDRINE SULFATE	240 mg

Inactive Ingredients

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

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
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1	NDC:68016-724-69	10 in 1 BLISTER PACK; Type 0: Not a Combination Product	11/17/2004	
2	NDC:68016-724-15	15 in 1 BLISTER PACK; Type 0: Not a Combination Product	11/17/2004	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA076557	11/17/2004		

Labeler - Chain Drug Consortium, LLC (101668460)

Registrant - Sun Pharmaceutical Industries Inc. (146974886)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		051565745	MANUFACTURE(68016-724)

Revised: 12/2019

Chain Drug Consortium, LLC