

LORATADINE AND PSEUDOEPHEDRINE SULFATE- loratadine and pseudoephedrine sulfate tablet, film coated, extended release
STRATEGIC SOURCING SERVICES

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. (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 McKesson

One Post Street, San Francisco, CA 94104

www.sunmarkbrand.com

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

sunmark®

**COMPARE TO CLARITIN-D® 24 HOUR
TABLETS ACTIVE INGREDIENTS****

NDC 49348-543-57

24 HOUR

Original Prescription Strength

allergy & congestion

lorata•dine D

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

Extended-Release Tablets

Indoor & 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

NON-DROWSY*

15 Extended-Release Tablets

***When taken
as directed.**

See Drug

Facts Panel.

sunmark®
allergy & congestion
lorata-dine D
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COMPARE TO CLARITIN-D® 24 HOUR
TABLETS ACTIVE INGREDIENTS**
NDC 49348-543-57

24 HOUR
Original Prescription Strength

Non Varnish Area

Batch No.

Expiration Date

** All trademarks are property of their respective owners. This product
is not affiliated with the makers/owners of Claritin-D®.

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MEKESON
Pharmaceuticals

Authorized Quality Product
Distributed by McKesson
One Park Street, San Francisco, CA 94104
Phone: 1-800-451-4545
Please visit us at www.mckesson.com



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Drug Facts (continued)

Other information
■ sodium: contains 10 mg/tablet
■ calcium: contains 25 mg/tablet
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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

Questions? call 1-800-451-7984

Drug Facts

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(in each tablet)
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Pseudoephedrine sulfate, USP 240 mg.....Nasal decongestant

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ask a doctor
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ask a doctor
■ consumers with liver or kidney disease
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Drug Facts (continued)

5173394

5173394

LORATADINE AND PSEUDOEPHEDRINE SULFATE

loratadine and pseudoephedrine sulfate tablet, film coated, extended release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49348-543
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, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FERROSO FERRIC 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:49348-543-01	10 in 1 BLISTER PACK; Type 0: Not a Combination Product	11/17/2004	

2	NDC:49348-543-57	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 - STRATEGIC SOURCING SERVICES (116956644)

Establishment			
Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		051565745	MANUFACTURE(49348-543)

Revised: 7/2020

STRATEGIC SOURCING SERVICES