LORATADINE AND PSEUDOEPHEDRINE- loratadine and pseudoephedrine tablet, extended release
Ohm Laboratories Inc.

Loratadine and Pseudoephedrine

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
- 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: Ohm Laboratories Inc.
1385 Livingston Avenue
North Brunswick, NJ 08902

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

NDC 51660-724-01

Original Prescription Strength

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

Non-Drowsy**

24
HOUR
RELIEF

Allergy & Congestion

Relief-D

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

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

10 Extended-Release Tablets

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

Actual Size

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Questions? call 1-800-406-7984

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

Non Varnish Area

Satisfaction guaranteed – Or we'll replace it or give you your money back. For questions or comments or to report an undesired reaction or side effect, please call **1-888-287-1915.**

Batch No.

Expiration Date:

Actual Size

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10 Extended-Release Tablets

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- Sneezing • Runny nose • Itchy, watery eyes
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Relief of:

Indoor & Outdoor Allergies

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Pseudoephedrine Sulfate, USP 240 mg/Nasal Decongestant

Allergy & Congestion Relief-D

Non-Drowsy**

24 HOUR RELIEF

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

Original Prescription Strength

NDC 51660-724-01

Distributed by: Ohm Laboratories Inc.
1385 Livingston Avenue
North Brunswick, NJ 08902
* All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Claritin-D®.

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Pseudoephedrine sulfate, USP 240 mg ..... Nasal decongestant

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Drug Facts (continued)

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LORATADINE AND PSEUDOEPHEDRINE

loratadine and pseudoephedrine tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51660-488
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 (1200000 MW) (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	**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:51660-488-69	10 in 1 BLISTER PACK; Type 0: Not a Combination Product	11/17/2004	
2	NDC:51660-488-15	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 - Ohm Laboratories Inc. (184769029)

Registrant - Ohm Laboratories Inc. (184769029)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(51660-488)

Revised: 6/2018 Ohm Laboratories Inc.