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

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?

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

Keep the Carton. It contains important information.

See end panel for expiration date.

Distributed by:

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

PACKAGE LABEL. PRINCIPAL DISPLAY PANEL

NDC 51660-491-69

Original Prescription Strength

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

NON-DROWSY**

Allergy Relief & Nasal Decongestant

24 Hour Allergy Relief

Loratadine, USP 10 mg/Antihistamine

Pseudoephedrine Sulfate, USP 240 mg/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**

Allergy & Congestion 10 Extended-Release Tablets

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

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

10's Blister Carton

Principal Display Panel

NDC 51660-491-15

Original Prescription Strength

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

NON-DROWSY**

Allergy Relief & Nasal Decongestant

24 Hour Allergy Relief

Loratadine, USP 15 mg/Antihistamine

Pseudoephedrine Sulfate, USP 240 mg/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**

Allergy & Congestion 15 Extended-Release Tablets

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

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LORATADINE AND PSEUDOEPHEDRINE

loratadine and pseudoephedrine tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51660-491
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)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

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:51660-491-69	10 in 1 BLISTER PACK; Type 0: Not a Combination Product	01/15/2020	
2	NDC:51660-491-15	15 in 1 BLISTER PACK; Type 0: Not a Combination Product	01/15/2020	

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 - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	MANUFACTURE(51660-491)