

**LORATADINE AND PSEUDOEPHEDRINE SULFATE- loratadine and pseudoephedrine sulfate tablet, film coated, extended release**  
**Amerisource Bergen**

-----  
**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

**PRINCIPAL DISPLAY PANEL**

**GOOD NEIGHBOR PHARMACY®**

**Compare to active ingredients in Claritin-D® 24 hour\*\***

**NDC 46122-0167-52**

**Non-Drowsy\***

**24 HOUR**

**Allergy & Congestion Relief**

**pseudoephedrine sulfate, USP 240 mg/nasal decongestant**

**loratadine, USP 10 mg/antihistamine**

**Indoor & Outdoor Allergies**

**Extended-Release Tablets**

**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 tablets**

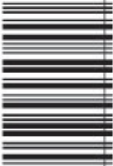
**\*When taken as directed.**

**See Drug Facts Panel.**

**Distributed by: AmerisourceBergen**

**5098864/R1012**

5098864



**Drug Facts (continued)**

- reduces swelling of nasal passages
- 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, psychotic, 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
  - trouble urinating due to an enlarged prostate gland
  - liver or kidney disease

**Directions**

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  
 ask a doctor

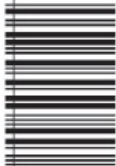
consumers with liver or kidney disease: ask a doctor

**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.

5098864



**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

Compare to active ingredients in  
**Claritin-D® 24 Hour\*\***  
 NDC 46122-0167-52



Non-Drowsy\* **24 HOUR**

# Allergy & Congestion Relief

pseudoephedrine sulfate, USP 240 mg/nasal decongestant  
 loratadine, USP 10 mg/antihistamine  
 Indoor & Outdoor Allergies

## Extended-Release Tablets

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 tablets

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

**Drug Facts (continued)**

- 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, polydioxane, pregelatinized starch, propylene glycol, sheilac 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.

R1012 ABC# 660-643  
 0 87701440392 7

Distributed by:  
 AmeriSourceBergen  
 1300 Morris Drive  
 Chesterbrook,  
 PA 19087  
 Visit us at: [www.goodneighborpharmacy.com](http://www.goodneighborpharmacy.com)



Expiration Date:

Batch No.

Non Varnish Area

\*\*Good Neighbor Pharmacy® Allergy & Congestion Relief is not manufactured or distributed by MSD Consumer Care, Inc., owner of the registered trademark Claritin-D® 24 Hour.

# LORATADINE AND PSEUDOEPHEDRINE SULFATE

loratadine and pseudoephedrine sulfate tablet, film coated, extended release

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:46122-167
<b>Route of Administration</b>	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:7CUC9DDI9F)	PSEUDOEPHEDRINE SULFATE	240 mg

## Inactive Ingredients

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

## Product Characteristics

<b>Color</b>	white (White to Off-White)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	RX724
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
---	-----------	---------------------	----------------------	--------------------

1	NDC:46 122-167-52	10 in 1 BLISTER PACK		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
ANDA	ANDA076557	11/17/2004		

**Labeler** - Amerisource Bergen (007914906)

**Registrant** - Ranbaxy Pharmaceuticals Inc. (937890044)

**Establishment**

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		051565745	manufacture(46122-167)

Revised: 10/2012

Amerisource Bergen