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

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#### **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

IDMINITE ONG CHIMTON I / VOOTE ONG AVOT	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<sup>®</sup>24 hour\*\*

NDC 46122-0167-52

Non-Drowsy\*

24 HOUR

Allergy & Congestion Relief

pseudoephedrine sulfate, USP 240 mg/nasal decongestant

# loratadine, USP 10 mg/antihis tamine

# **Indoor & Outdoor Allergies**

# **Extended-Release Tablets**

#### Relief of:

- Nas al 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: Ameris ourceBergen

5098864/R1012

■ TAMPER EVIDENT: DO NOT USE IF BLISTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING. 🖜 ■ calcium: contains 25 mg/tablet sodium: contains 10 mg/tablet Other information consumers with liver or kidney disease | ask a doctor sak a doctor children under 12 years of age I tablet daily with a full glass of water; not more than I tablet in 24 hours adults and children 12 years and over ■ do not divide, crush, chew or dissolve the tablet Directions If pregnant or breast-feeding, sak 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). ■ nervousness, dizziness or sleeplessness occurs Stop use and sak 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 When using this product do not take more than directed. Taking more than directed may cause drowsiness. liver or kidney disease. Your doctor should determine it you need a different dose. ■ trouble urinating due to an enlarged prostate gland ■ diabetes ■ µigh blood pressure ■ thyroid disease ■ heart disease Ask a doctor before use if you have do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

USes 

Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

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Temporarily relieves these symptoms due to have the nose or throat Nasal decongestant Pseudoephedrine sulfate, USP 240 mg. Active ingredients (in each tablet)
Loratadine, USP 10 mg Antinistamine Purpose urug Facts

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■ temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies

It you have ever had an allergic reaction to this product or any of its ingredients

■ temporarily restores freer breathing through the nose

■ reduces swelling of nasal passages Drug racts (continued)

Do not use Warnings

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

NDC 46122-0167-52

GOOD **NEIGHBOR** 

jemboraniy relieves sinus congestion and pressure

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



#### Questions? call 1-800-406-7984

oxide black, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, svegelatinized starch, propylene glycol, shellac glaze, sodium alginate, sodium citrate, talc and titanium dioxide INACTIVE INGREGIENTS calcium carbonate, colloidal silicon dioxide, hydroxypropyl cellulose, hypromellose, iron

- protect from light and store in a dry place
- store between 20° C to 25° C (68° F to 77° F)

Drug Facts (continued)

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



Non Varnish Area

owner of the registered trademark \*\*Good Neighbor Pharmacya Allergy & Congestion Relief is not manufactured or distributed by MSD Consumer Care, Inc., owner of the registered tradema Claritin-D<sup>a</sup> 24 Hour.



# LORATADINE AND PSEUDOEPHEDRINE SULFATE

loratadine and pseudoephedrine sulfate tablet, film coated, extended release

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:46122-167
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
LORATADINE (LORATADINE)	LORATADINE	10 mg		
PSEUDO EPHEDRINE SULFATE (PSEUDO EPHEDRINE)	PSEUDOEPHEDRINE SULFATE	240 mg		

Inactive Ingredients			
Ingredient Name	Strength		
CALCIUM CARBONATE			
COLLO IDAL SILICON DIO XIDE			
HYDROXYPROPYL CELLULOSE			
HYPROMELLOSES			
FERROSOFERRIC OXIDE			
LACTOSE MONOHYDRATE			
MAGNESIUM STEARATE			
CELLULOSE, MICRO CRYSTALLINE			
POLYETHYLENE GLYCOLS			
PO VIDO NE			
STARCH, PREGELATINIZED CORN			
PROPYLENE GLYCOL			
SHELLAC			
SODIUM ALGINATE			
SODIUM CITRATE			
TALC			
TITANIUM DIO XIDE			

Product Characteristics			
Color	white (White to Off-White)	Score	no score
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	RX724
Contains			

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46122-167-52	10 in 1 BLISTER PACK		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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 (46 122-167)	

Revised: 10/2012 Amerisource Bergen