LORATADINE AND PSEUDOEPHEDRINE SULFATE- loratadine and pseudoephedrine sulfate tablet, film coated, extended release
Select Brand

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

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

NDC 15127-717-05

NON-DROWSY*

select brand®

Original Prescription Strength

Allergy Relief and Nasal Decongestant

24 Hour Formula

Loratadine, USP 10 mg/Antihistamine

Pseudoephedrine Sulfate, USP 240 mg/Nasal Decongestant

Indoor & Outdoor Allergies

Allergy & Congestion

RELIEF OF:

Nasal and Sinus Congestion Due to Colds or Allergies

Sneezing; Runny Nose

Itchy, Watery Eyes; Itchy Throat

or Nose Due to Allergies

5 Extended-Release Tablets

*When taken as directed. See Drug Facts Panel.

Distributed by: SELECT BRAND DISTRIBUTORS

5079457/R0710

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

NDC 15127-717-05

NON-DROWSY*

select brand®
the lower price name brand

Original Prescription Strength

24 Hour Formula

Allergy Relief and Nasal Decongestant

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

Indoor & Outdoor Allergies

Allergy & Congestion

RELIEF OF:
Nasal and Sinus Congestion
Due to Colds or Allergies
Sneezing; Runny Nose
Itchy, Watery Eyes; Itchy Throat
or Nose Due to Allergies

* When taken as directed. See Drug Facts Panel.

5 Extended-Release Tablets

†This product is not manufactured or distributed by Schering-Plough HealthCare Products, Inc., owner of the registered trademark Claritin-D® 24 Hour.

Distributed by:
SELECT BRAND DISTRIBUTORS
Pine Bluff, AR 71603 USA
AC (870) 535-3635

R0710

0 15127 01490 8

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

Expiration Date:

Batch No.

Non Varnish Area

5079457

5079457

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, povidone, pregelatinized starch, propylene glycol, shellac glaze, sodium alginate, sodium citrate, talc and titanium dioxide

Questions? call 1-800-406-7984

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 relieves sinus congestion and pressure
■ 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
■ 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.
■ heart disease ■ thyroid disease

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. ▼

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

LORATADINE AND PSEUDOEPHEDRINE SULFATE

loratadine and pseudoephedrine sulfate tablet, film coated, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:15127-717
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)	
COLLOIDAL SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERROSOFERRIC 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			
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:15127-717-15	15 in 1 BLISTER PACK		
2	NDC:15127-717-05	5 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 - Select Brand (043562370)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		051565745	manufacture(15127-717)

Revised: 9/2012 Select Brand