

LORATADINE AND PSEUDOEPHEDRINE SULFATE- loratadine and pseudoephedrine sulfate tablet, film coated, extended release
Topco Associates LLC

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 1-888-423-0139

PRINCIPAL DISPLAY PANEL

TopCare®

NDC 36800-724-69

NON-DROWSY*

24 HOUR

Original Prescription Strength

Allergy Relief - D

**PSEUDOEPHEDRINE SULFATE, USP 240 mg/NASAL DECONGESTANT
LORATADINE, USP 10 mg/ANTIHISTAMINE EXTENDED RELEASE TABLETS**

Indoor & Outdoor Allergies

Relief of:

Nasal and Sinus Congestion Due to Cold or Allergies

Sneezing; Runny Nose; Itchy, Watery Eyes

Itchy Throat or Nose Due to Allergies

10 EXTENDED RELEASE TABLETS

COMPARE TO CLARITIN-D[®] 24 HOUR active ingredients[†]

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

DIST.BY TOPCO ASSOCIATES LLC

5095191/R0412



5095191

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

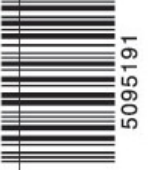
- Do not use
- if you have ever had an allergic reaction to this product or any of its ingredients
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the 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
 - heart disease
 - thyroid disease
 - trouble urinating due to an enlarged prostate gland
 - liver or kidney disease

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
- ask a doctor

Other Information

- calcium: contains 25 mg/tablet
- sodium: contains 10 mg/tablet
- TAMPER EVIDENT: DO NOT USE IF BLISTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING.



5065191

Drug Facts

Active Ingredients (in each tablet)

Loratadine, USP 10 mg
Pseudoephedrine sulfate, USP 240 mg
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

NDC 36800-724-69

NON-DROWSY* 24 HOUR

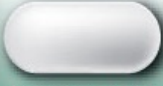
Original Prescription Strength

Allergy Relief-D

PSEUDOEPHEDRINE SULFATE, USP 240 mg/NASAL DECONGESTANT
LORATADINE, USP 10 mg/ANTIHISTAMINE EXTENDED RELEASE TABLETS

Indoor & Outdoor Allergies

Relief of:
Nasal and Sinus Congestion Due to Cold 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.



COMPARE TO
CLARITIN-D® 24 HOUR
active ingredients†

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

Questions? call 1-888-423-0139

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



R0412

TopCare product is laboratory tested to guarantee its highest quality. See end panel for expiration date.

DIST. BY TOPCO ASSOCIATES, LLC
7711 GROSS POINT ROAD
SKOKIE, IL 60077 ©TOPCO DHMR412
QUESTIONS? 1-888-423-0139
topcare@topco.com

Non Varnish Area

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

Expiration Date:

Batch No.

LORATADINE AND PSEUDOEPHEDRINE SULFATE

loratadine and pseudoephedrine sulfate tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-724
Route of Administration	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

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:36800-724-69	10 in 1 BLISTER PACK		
2	NDC:36800-724-15	15 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 - Topco Associates LLC (006935977)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		051565745	manufacture(36800-724)

Revised: 12/2012

Topco Associates LLC