

LORATADINE AND PSEUDOEPHEDRINE SULFATE- loratadine and pseudoephedrine sulfate tablet, film coated, extended release
Publix Super Markets 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

PRINCIPAL DISPLAY PANEL - 10 Tablet Blister Pack Carton

NDC 56062-724-69

24-HOUR

allergy relief

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

ALLERGY & CONGESTION

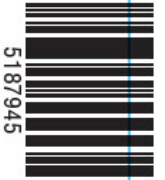
24-hour relief of:

- Nasal & sinus congestion due to colds or allergies
- Sneezing; runny nose; itchy, watery eyes & itchy nose or throat due to allergies

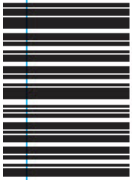
10
EXTENDED-RELEASE
TABLETS

ACTUAL SIZE

*Compare to the active ingredients
in Claritin-D[®] 24 Hour



5187945



5187945

Drug Facts (continued)

- 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.

Other Information

- sodium: contains 10 mg/tablet
- calcium: contains 25 mg/tablet
- TAMPER EVIDENT: DO NOT USE IF BUSTERS 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

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

Drug Facts (continued)

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).

Drug Facts

Active ingredients (in each tablet)

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

NDC 56062-724-69



24-HOUR

allergyreliefD

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

ALLERGY & CONGESTION

24-hour relief of:

- Nasal & sinus congestion due to colds or allergies
- Sneezing; runny nose; itchy, watery eyes & itchy nose or throat due to allergies



ACTUAL SIZE

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

10 EXTENDED-RELEASE TABLETS

Expiration Date:
Batch No.

Non Varnish Area

Keep the carton. It contains important information.

See end panel for expiration date.

active 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.

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LORATADINE AND PSEUDOEPHEDRINE SULFATE

loratadine and pseudoephedrine sulfate tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56062-724
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)	
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	
SODIUM CITRATE, UNSPECIFIED FORM (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:56062-724-69	10 in 1 BLISTER PACK; Type 0: Not a Combination Product	11/17/2004	
2	NDC:56062-724-15	15 in 1 BLISTER PACK; Type 0: Not a Combination Product	11/17/2004	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076557	11/17/2004	

Labeler - Publix Super Markets Inc (006922009)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		051565745	manufacture(56062-724)

Revised: 10/2018

Publix Super Markets Inc