

# **LORATADINE AND PSEUDOEPHEDRINE- loratadine and pseudoephedrine sulfate tablet, extended release**

**Rite Aid**

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**allergy relief & nasal decongestant**

## **Drug Facts**

<b>Active ingredients (in each tablet)</b>	<b>Purpose</b>
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
- 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**

**DISTRIBUTED BY: RITE AID, 30 HUNTER LANE, CAMP HILL, PA 17011**

**PRINCIPAL DISPLAY PANEL - 15 Tablet Blister Pack Carton**

24 HOUR

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

NDC 11822-9990-5

ORIGINAL PRESCRIPTION STRENGTH

ALLERGY RELIEF &

NASAL DECONGESTANT

LORATADINE, USP 10 mg / PSEUDOEPHEDRINE SULFATE, USP 240 mg

ANTIHISTAMINE & NASAL DECONGESTANT

NON-DROWSY\*

INDOOR / OUTDOOR ALLERGIES

24 HOUR RELIEF OF

Nasal & 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.

ACTUAL SIZE

15

EXTENDED-

RELEASE TABLETS

ORIGINAL PRESCRIPTION STRENGTH  
**ALLERGY RELIEF &  
 NASAL DECONGESTANT**

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**NON-DROWSY\***  
 INDOOR / OUTDOOR ALLERGIES  
 24 HOUR RELIEF OF

Nasal & sinus congestion due to colds or allergies  
 Sneezing • Runny nose • Itchy, watery eyes  
 Itchy throat or nose due to allergies

ACTUAL SIZE



\*WHEN TAKEN AS DIRECTED, SEE DRUG FACTS PANEL.

**15**  
 EXTENDED-  
 RELEASE TABLETS

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

R1021  
 DISTRIBUTED BY:  
 RITE AID  
 30 HUNTER LANE,  
 CAMP HILL, PA 17011

**SATISFACTION  
 GUARANTEE**  
 If you're not satisfied, we'll  
 happily return your money.



Non Varnish Area

Batch No.

Expiration Date:

\*\*All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Claritin-D®.

**Drug Facts (continued)**

**Other Information**  
 ■ sodium: contains 10 mg/tablet  
 ■ calcium: contains 25 mg/tablet  
 ■ TAMPER EVIDENT: DO NOT USE IF BUSTER 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, polydioxane, pregelatinized starch, propylene glycol, shealac glaze, sodium alginate, sodium citrate, talc and titanium dioxide

Questions? call 1-800-406-7984

**Drug Facts**

**Active Ingredients (in each tablet)**  
 Loratadine, USP 10 mg.....Antihistamine  
 Pseudoephedrine sulfate, USP 240 mg.....Nasal decongestant

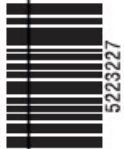
**Purpose**  
 Relieves these symptoms due to hay fever or other upper respiratory allergies: sneezing, itchy, watery eyes, runny nose, itching of the nose or throat, reduces swelling of nasal passages, temporarily relieves sinus congestion and pressure common cold, hay fever or other upper respiratory 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 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.

**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 common cold, hay fever or other upper respiratory allergies temporarily restores free breathing through the nose

**Directions**  
 ■ do not divide, crush, chew or dissolve the tablet  
 ■ 1 tablet daily with a full glass of water; not more than 12 years and over  
 ■ children under 12 years of age ask a doctor  
 ■ consumers with liver or kidney disease ask a doctor

**Drug Facts (continued)**  
 Ask a doctor before use if you have  
 ■ heart disease  
 ■ thyroid disease  
 ■ diabetes  
 ■ high blood pressure  
 ■ 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 breastfeeding, 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).



**PRINCIPAL DISPLAY PANEL - 10 Tablet Blister Pack Carton**

NDC 11822-9990-0

24 HOUR

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

ORIGINAL PRESCRIPTION STRENGTH

ALLERGY RELIEF &  
NASAL DECONGESTANT

LORATADINE, USP 10 mg / PSEUDOEPHEDRINE SULFATE, USP 240 mg

ANTIHISTAMINE & NASAL DECONGESTANT

NON-DROWSY\*

INDOOR / OUTDOOR ALLERGIES

24 HOUR RELIEF OF

Nasal & 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.

ACTUAL SIZE

10

EXTENDED-  
RELEASE TABLETS

5223226

Expiration Date:

Batch No.

Non Varnish Area

R1021

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

NDC 11822-9990-0  
**24 HOUR**

# ORIGINAL PRESCRIPTION STRENGTH ALLERGY RELIEF & NASAL DECONGESTANT

LORATADINE, USP 10 mg / PSEUDOEPHEDRINE SULFATE, USP 240 mg

**ANTIHISTAMINE & NASAL DECONGESTANT**

**NON-DROWSY\***  
**INDOOR / OUTDOOR ALLERGIES**  
**24 HOUR RELIEF OF**

Nasal & sinus congestion due to colds or allergies  
Sneezing • Runny nose • Itchy, watery eyes  
Itchy throat or nose due to allergies

ACTUAL SIZE

**10**  
**EXTENDED-  
RELEASE TABLETS**



\*WHEN TAKEN AS DIRECTED. SEE DRUG FACTS PANEL.

**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, sodium chloride, and titanium dioxide

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

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

## 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 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 heart disease, thyroid disease, high blood pressure, diabetes, trouble urinating due to an enlarged prostate gland or 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.

## 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 before use.
- If pregnant or breast-feeding, ask a health professional for advice before using.
- 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 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.

**Drug Facts**  
**Active ingredients (in each tablet)**  
Loratadine, USP 10 mg.....Antihistamine  
Pseudoephedrine sulfate, USP 240 mg.....Nasal decongestant

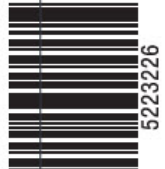
**Purpose**  
Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: sneezing, itchy, watery eyes, runny nose, itching of the nose or throat.

\*\* All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Claritin-D®.

**DISTRIBUTED BY:**  
RITE AID, 30 HUNTER LANE  
GAMP HILL, PA 17011 www.riteaid.com

**SATISFACTION GUARANTEE:**  
If you're not satisfied, we'll happily refund your money.

ITEM 331455  
0 11822 33155 5



**LORATADINE AND PSEUDOEPHEDRINE**

loratadine and pseudoephedrine sulfate tablet, extended release

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11822-9990
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>LORATADINE</b> (UNII: 7AJ03BO7QN) (LORATADINE - UNII: 7AJ03BO7QN)	LORATADINE	10 mg
<b>PSEUDOEPHEDRINE SULFATE</b> (UNII: Y9DL7QPE6B) (PSEUDOEPHEDRINE - UNII: 7CUC9DDI9F)	PSEUDOEPHEDRINE SULFATE	240 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>HYDROXYPROPYL CELLULOSE (1600000 WAMW)</b> (UNII: RFW2ET671P)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>SODIUM ALGINATE</b> (UNII: C269C4G2ZQ)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>FERROSO FERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	

**Product Characteristics**

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL	<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:11822-9990-5	1 in 1 CARTON	11/17/2004	
1		15 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:11822-9990-0	1 in 1 CARTON	11/17/2004	
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

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

**Labeler** - Rite Aid (014578892)

## Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(11822-9990)

Revised: 5/2022

Rite Aid