

**LORATADINE AND PSEUDOEPHEDRINE- loratadine and pseudoephedrine tablet, extended release**  
**STRATEGIC SOURCING SERVICES LLC**

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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

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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

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**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 **833-358-6431** Monday to Friday 9:00 am to 7:00 pm EST

**Distributed by:** McKesson Corp., via Strategic Sourcing Services LLC. Memphis, TN

38141

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

NDC 70677-1018-1

COMPARE TO CLARITIN-D®  
24 HOUR ACTIVE INGREDIENTS†

Foster & Thrive™

ORIGINAL PRESCRIPTION STRENGTH

Allergy Relief-D

Loratadine, USP 10 mg/ANTIHISTAMINE  
Pseudoephedrine Sulfate, USP 240 mg/NASAL DECONGESTANT

Non-Drowsy\*

Indoor & Outdoor Allergies | Allergy & Congestion

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

**Drug Facts (continued)**

**Warnings**

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

**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

**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 (continued)**

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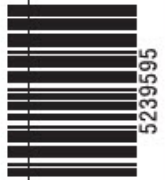
**Drug Facts**

**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 709677-1018-1

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- Sneezing; Runny Nose; Itchy, Watery Eyes; Itchy Throat or Nose Due to Allergies

**10 Extended-Release Tablets**

**ACTUAL SIZE**

**Expiration Date:**

**Batch No.:**

**Non Varnish Area**

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

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Money Back Guarantee  
www.fosterandthrive.com  
PLD-A604A LB000810 Rev 04/23

**KEEP THE CARTON. IT CONTAINS IMPORTANT INFORMATION. SEE END PANEL FOR EXPIRATION DATE.**

**Questions? Call 833-358-6431 Monday to Friday 9:00 am to 7:00 pm EST**

one piece, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinylpyrrolidone, pregelatinized starch, propylene glycol, shealac glaze, sodium alginate, sodium citrate, talc and titanium dioxide

**Drug Facts** (continued)  
 Inactive ingredients: calcium carbonate, colloidal silicon dioxide, hydroxypropyl cellulose, hypromellose, iron

# LORATADINE AND PSEUDOEPHEDRINE

loratadine and pseudoephedrine tablet, extended release

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70677-1018
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<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

Ingredient Name	Strength
<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:70677-1018-1	1 in 1 CARTON	08/10/2023	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:70677-1018-2	1 in 1 CARTON	08/10/2023	
2		15 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	08/10/2023	

**Labeler** - STRATEGIC SOURCING SERVICES LLC (116956644)

## Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(70677-1018)

Revised: 8/2023

STRATEGIC SOURCING SERVICES LLC