# LORATADINE- loratadine solution STRATEGIC SOURCING SERVICES LLC

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Loratadine

**Drug Facts** 

# Active ingredient (in each 5 mL teaspoonful)

Loratadine 5 mg

# **Purpose**

**Antihistamine** 

#### Uses

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- itchy, watery eyes
- sneezing
- itching of the nose or throat

# **Warnings**

**Do not use**if you have ever had an allergic reaction to this product or any of its ingredients.

**Ask a doctor before use if you have**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.

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**

use only with enclosed dosing cup

years ariu uver	hours 1 teaspoonful (tsp) daily; do not take more than 1 teaspoonful (tsp) in 24 hours	
children 2 to under 6 years of age		
children under 2 years of age	ask a doctor	
consumers with liver or kidney disease	ask a doctor	

#### Other information

- do not use if bottle wrap imprinted with "SEALED FOR SAFETY" is broken or missing.
- see bottom panel for lot number and expiration date
- store between 20° and 25°C (68° and 77°F)

## **Inactive ingredients**

artificial peach flavor, citric acid monohydrate, glycerin, propylene glycol, purified water, sodium benzoate, sodium metabisulfite, sucrose

### Questions?

call **833-358-6431** 

**Distributed by:**McKesson Corp., via Strategic Sourcing Services LLC. Memphis, TN 38141

#### PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

NDC 70677-1057-1

COMPARE TO CHILDREN'S CLARITIN ® ACTIVE INGREDIENT\*

Foster & Thrive™

ORIGINAL PRESCRIPTION STRENGTH

Children's Allergy

Loratadine Oral Solution USP, 5 mg/5 mL ANTIHISTAMINE Allergy

Indoor & Outdoor Allergies

24 hour relief of:

- Runny Nose
- Itchy, Watery Eyes
- Sneezing

• Itchy Throat or Nose

Non-Drowsy\*\*

WARNING: Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions.

Ages 2 years & older Dye Free FRUIT FLAVOR DOSING CUP ENCLOSED

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

4 FL OZ (120 mL)



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#### SEALED WITH PRINTED NECKBAND

Drug Facts Active ingredient (in each 5 mL teaspoonful) Loratadine 5 mg....

.Antihistamine

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Directions • use only with enclosed dosing cup

adults and children 6 years and over 2 tesspoonfuls (tsp) daily, do not take more than 2 tesspoonfuls (tsp) in 24 hours

1 teaspoonful (tsp) daily, do not take more than 1 teaspoonful (tsp) in 24 hours children under ask a doctor consumers with liver ask a doctor or kidney disease

- Other information

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   see bottom panel for lot rumbs and expiration date

   store between 20" and 25"C (68° and 77"F)

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Questions? cal 833-358-6431

NDC70677-1057-1

CLARITIN® ACTIVE INGREDIEN

Foster & Thrive™

ORIGINAL PRESCRIPTION STRENGTH

## Children's

# Allergy

**Loratadine Oral Solution** USP, 5 mg/5 mL ANTIHISTAMINE Allergy

Indoor & Outdoor Allergies 24 hour relief of:

Runny Nose • Itchy, Watery Eyes Sneezing Itchy Throat or Nose

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4 FL OZ (120 mL)

Foster & Thrive™

- √ Ages 2 years & older
- ✓ Indoor & Outdoor **Allergies**
- √ 24 hour relief of:
- Runny Nose
- Sneezing
- Itchy, Watery Eyes
- · Itchy Throat or Nose

#### FRUIT FLAVOR

- √ Alcohol Free
- √ Dye Free
- √ Non-Drowsy\*\*

\*All trademarks are properly of their respective owners. This product is not affiliated with the makers/owners of Children's Clarifin<sup>a</sup>.

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NDC70677-1057-1

CLARITIN® ACTIVE INGREDIENT\*

Foster & Thrive™

ORIGINAL PRESCRIPTION STRENGTH

# Children's Allergy

**Loratadine Oral Solution** USP, 5 mg/5 mL ANTIHISTAMINE Allergy

Indoor & Outdoor Allergies 24 hour relief of:

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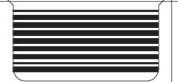
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4 FL OZ (120 mL)





NO VARNISH/ NO AQ NO COPY / NO COLOR THIS FLAP FOR LOT # AND EXP DATE PRINT

## LORATADINE

loratadine solution

#### **Product Information**

HUMAN OTC DRUG NDC:70677-1057 **Product Type Item Code (Source)** 

**Route of Administration** ORAL

**Active Ingredient/Active Moiety** 

Ingredient Name	Basis of Strength	Strength
LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN)	LORATADINE	5 mg in 5 mL

Inactive Ingredients		
Ingredient Name	Strength	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)		
GLYCERIN (UNII: PDC6A3C0OX)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SODIUM METABISULFITE (UNII: 4VON5FNS3C)		
SUCROSE (UNII: C151H8M554)		
WATER (UNII: 059QF0KO0R)		

Product Characteristics		
Color	yellow (colorless to slightly yellow)	Score
Shape		Size
Flavor	FRUIT (peach)	Imprint Code
Contains		

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:70677- 1057-1	1 in 1 CARTON	08/01/2023		
1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076805	08/01/2023	

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

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
Sun Pharma Canada Inc.		243339023	manufacture(70677-1057)		

Revised: 7/2025 STRATEGIC SOURCING SERVICES LLC