

CHILDRENS LORATADINE- loratadine solution
Sun Pharmaceutical Industries, Inc.

Children's Loratadine

Drug Facts

Active ingredient (in each 5 mL)

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
- mL=milliliter

adults and children 6 | 10 mL daily; do not take more

years and over	than 10 mL in 24 hours
children 2 to under 6 years of age	5 mL daily; do not take more than 5 mL in 24 hours
children under 2 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

Other information

- **each 5 mL contains:** sodium 5 mg.
- **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 **1-866-923-4914**

Distributed by:

Ohm Laboratories Inc.

New Brunswick, NJ 08901

Made In Israel

PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

NDC 51672-2073-8

Children's

Loratadine

Oral Solution

USP, 5 mg/5 mL

SEALED WITH PRINTED NECKBAND

Drug Facts

Active ingredient (in each 5 mL) Purpose
Loratadine 5 mg.....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
• mL= milliliter

adults and children 6 years and over	10 mL daily; do not take more than 10 mL in 24 hours
children 2 to under 6 years of age	5 mL daily; do not take more than 5 mL in 24 hours
children under 2 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

Other information
• each 5 mL contains: sodium 5 mg
• **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 1-866-923-4914

NDC 51672-2073-8

Compare to the active ingredient in Children's Claritin®*

Children's Loratadine Oral Solution USP, 5 mg/5 mL

(Antihistamine) ALLERGY

Indoor & Outdoor Allergies

083
5200647-0525-06

NDC 51672-2073-8

Compare to the active ingredient in Children's Claritin®*

ohm
LABORATORIES INC.

a SUN PHARMA company

Original Prescription Strength

Children's Loratadine Oral Solution USP, 5 mg/5 mL

(Antihistamine) ALLERGY

Indoor & Outdoor Allergies

Non-Drowsy!

24 Hour Relief of:

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

Ages 2 years and older

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

Dosage Cup Enclosed



Dye Free Fruit Flavor

4 FL OZ (120 mL)

*When taken as directed. See Drug Facts Panel.

NDC 51672-2073-8

Compare to the active ingredient in Children's Claritin®*

Original Prescription Strength

Children's Loratadine Oral Solution USP, 5 mg/5 mL

(Antihistamine) ALLERGY

Indoor & Outdoor Allergies

- 24 Hour Relief
- Alcohol Free
- Dye Free

Dosage Cup Enclosed



Dye Free Fruit Flavor

*OHM and OHM Logo are trademarks of Ohm Laboratories, Inc. All other trademarks are the property of their respective owners.

Distributed by:
Ohm Laboratories Inc.
New Brunswick, NJ 08901
Made in Israel

NDC 51672-2073-8

Compare to the active ingredient in Children's Claritin®*

ohm
LABORATORIES INC.

a SUN PHARMA company

Original Prescription Strength

Children's Loratadine Oral Solution USP, 5 mg/5 mL

(Antihistamine) ALLERGY

Indoor & Outdoor Allergies

Non-Drowsy!

24 Hour Relief of:

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

Ages 2 years and older

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

Dosage Cup Enclosed



Dye Free Fruit Flavor

4 FL OZ (120 mL)

*When taken as directed. See Drug Facts Panel.





CHILDRENS LORATADINE

loratadine solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51672-2073
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LORATADINE (UNII: 7AJ03BO7QN) (LORATADINE - UNII: 7AJ03BO7QN)	LORATADINE	5 mg in 5 mL

Inactive Ingredients

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

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51672-2073-8	1 in 1 CARTON	08/20/2004	
1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:51672-2073-4	1 in 1 CARTON	08/20/2004	
2		60 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:51672-2073-5	1 in 1 CARTON	08/20/2004	
3		180 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	08/20/2004	

Labeler - Sun Pharmaceutical Industries, Inc. (146974886)

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceutical Industries Ltd.		600072078	manufacture(51672-2073)

Revised: 5/2025

Sun Pharmaceutical Industries, Inc.