

CHILDRENS LORATADINE- loratadine solution
Taro Pharmaceuticals U.S.A., Inc.

Children's 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

adults and children 6 years and over | 2 teaspoonfuls (tsp) daily; do not take more than 2

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

Other information

- **do not use if carton is opened, or if imprinted safety seal is broken or missing**
- see bottom panel for expiration date
- store between 20° to 25°C (68° to 77°F)

Inactive ingredients

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

Questions?

Call **1-866-923-4914**

Distributed by:

Taro Pharmaceuticals U.S.A., Inc.

Hawthorne, NY 10532

PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

NDC xxxxx-xxxx-x

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

GRAPE FLAVOR

Original Prescription Strength

Ages two years and older

Children's
Loratadine Syrup
(Loratadine Oral Solution)
5 mg/5 mL

Antihistamine

Grape Flavored Syrup

**24 Hour Non-Drowsy[†]
Allergy Relief**

**Indoor &
Outdoor
Allergies**

Relief of:

*Sneezing; Runny Nose,
Itchy, Watery Eyes,
Itchy Throat or Nose*

4 FL OZ (120 mL)

[†]When taken as directed. See Drug Facts Panel.

SEALED WITH PRINTED NECKBAND

Drug Facts

Active ingredient
(in each 5 mL teaspoonful) **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

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

Other information

- do not use if carton is opened, or if imprinted safety seal is broken or missing
- see bottom panel for expiration date
- store between 20° to 25°C (68° to 77°F)

Inactive ingredients
artificial grape flavor, citric acid monohydrate, glycerin, propylene glycol, purified water, sodium benzoate, sodium metabisulfite, sucrose

Questions? Call 1-866-923-4914

FPO

Children's Loratadine Syrup
(Loratadine Oral Solution)
5 mg/5 mL
Antihistamine

GRAPE FLAVOR Original Prescription Strength

Children's Loratadine Syrup
(Loratadine Oral Solution)
5 mg/5 mL
Antihistamine

GRAPE FLAVORED SYRUP

24 Hour Non-Drowsy* Allergy Relief Indoor & Outdoor Allergies

4 FL OZ (120 mL)

† When taken as directed. See Drug Facts Panel.

FPO

000
20233-0713-2

Children's Loratadine Syrup
(Loratadine Oral Solution)
5 mg/5 mL
Antihistamine

GRAPE FLAVORED SYRUP

24 Hour Allergy Relief Indoor & Outdoor Allergies

Children's Loratadine Syrup
(Loratadine Oral Solution)
5 mg/5 mL
Antihistamine

GRAPE FLAVORED SYRUP

24 Hour Non-Drowsy* Allergy Relief Indoor & Outdoor Allergies

4 FL OZ (120 mL)

† When taken as directed. See Drug Facts Panel.

FPO

Children's Loratadine Syrup
(Loratadine Oral Solution)
5 mg/5 mL
Antihistamine

GRAPE FLAVOR Original Prescription Strength

Children's Loratadine Syrup
(Loratadine Oral Solution)
5 mg/5 mL
Antihistamine

GRAPE FLAVORED SYRUP

24 Hour Non-Drowsy* Allergy Relief Indoor & Outdoor Allergies

4 FL OZ (120 mL)

† When taken as directed. See Drug Facts Panel.

FPO

CHILDRENS LORATADINE

loratadine solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51672-2085
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	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51672-2085-8	1 in 1 CARTON	08/20/2004	
1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:51672-2085-4	1 in 1 CARTON	08/20/2004	
2		60 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:51672-2085-5	1 in 1 CARTON	08/20/2004	
3		180 mL in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:51672-2085-1	1 in 1 CARTON	08/20/2004	
4		240 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	

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceutical Industries Ltd.		600072078	manufacture(51672-2085)

Revised: 12/2024

Taro Pharmaceuticals U.S.A., Inc.