

CHILDRENS NON-DROWSY 24-HOUR ALLERGY RELIEF- loratadine solution
Safeway Inc.

Children's Non-Drowsy*
24-Hour Allergy Relief

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.

Directions

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

Other information

- **safety sealed: do not use if imprinted safety seal is torn or missing**
- store between 2° and 25°C (36° and 77°F)

Inactive ingredients

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

DISTRIBUTED BY SAFEWAY INC.

P.O. BOX 99, PLEASANTON, CA 94566-0009

PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

NDC 21130-787-29

**Compare to
Children's Claritin®
active ingredient†**

**Children's
Non-Drowsy***

**24-Hour
Allergy Relief**

Loratadine Oral Solution

5 mg/5 mL

Antihistamine

Relieves:

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itching of Nose & Throat

Ages two years and older

*When taken as directed.

See Drug Facts panel.

Dosage cup enclosed

Dye-Free

**Grape Flavored
Alcohol Free**

4 FL OZ

(120 mL)

SAFEWAY™

SEALED WITH PRINTED NECKBAND

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*This product is not manufactured by Schering-Plough HealthCare Products Inc., the distributors of Children's Claritin®.

DISTRIBUTED BY SAFEWAY INC.
P.O. BOX 99, PLEASANTON, CA 94566-0099
1-888-SAFEWAY / www.safeway.com PRODUCT OF ISRAEL

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**24-Hour
Allergy Relief**

Loratadine Oral Solution
5 mg/5 mL
Antihistamine

*When taken as directed.
See Drug Facts panel.

484

70145-1209-1

NDC 21130-787-29

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Children's Claritin®
active ingredient†

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RD 09323 S3202

N 3 21130 78729 7

CHILDRENS NON-DROWSY 24-HOUR ALLERGY RELIEF

loratadine solution

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:21130-787

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:21130-787-29	1 in 1 CARTON		
1		120 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076805	08/20/2004	

Labeler - Safeway Inc. (009137209)

Registrant - Taro Pharmaceuticals U.S.A., Inc. (145186370)

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceutical Industries Ltd.		600072078	MANUFACTURE(21130-787)