

CHILDRENS LORATADINE- loratadine solution
American Sales Company

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.
- side effects occur. You may report side effects to FDA at **1-800-FDA-1088**.

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: American Sales Company
4201 Walden Avenue, Lancaster, NY 14086

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Carton

*Compare to the
Active Ingredient
in Children's
Claritin®**

CAREONE®

**24 HOUR/NON-DROWSY†
ALLERGY RELIEF**

**CHILDREN'S
LORATADINE**

*(Loratadine Oral Solution)
5 mg/5 mL Antihistamine*

**Dosage Cup
Enclosed**

DYE FREE

**GRAPE FLAVORED
SYRUP** *Ages two years and older*

Relief of:
**Sneezing, Runny Nose,
Itchy, Watery Eyes,
Itchy Throat or Nose**

† When taken as directed.
See Drug Facts Panel.

**4 FL OZ
(118 mL)**



SEALED WITH PRINTED NECKBAND

Drug Facts
Active ingredient
 (in each 5 mL) **Purpose**
 Loratadine 5 mg Antihistamine

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

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 4201 Walden Avenue, Lancaster, NY 14086
 © 2010 S&S BRANDS, INC. • www.Care1.info
 Quality guaranteed or your money back.
 Made in Israel.
 * This product is not manufactured or distributed by Schering-Plough HealthCare Products Inc., owner of the registered trademark Claritin®.

Compare to the Active Ingredient in Children's Claritin®*

CARONE®
 24 HOUR/NON-DROWSY ALLERGY RELIEF
CHILDREN'S LORATADINE
 (Loratadine Oral Solution)
 5 mg/5 mL Antihistamine

DYE FREE
GRAPE FLAVORED SYRUP Ages two years and older

Relief of:
 Sneezing, Runny Nose,
 Itchy, Watery Eyes,
 Itchy Throat or Nose

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CHILDRENS LORATADINE			
loratadine solution			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-085

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:41520-085-08	1 in 1 CARTON		
1		118 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 - American Sales Company (809183973)

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

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceutical Industries Ltd.		600072078	MANUFACTURE(41520-085)