# SUNMARK CHILDRENS LORATADINE- loratadine solution McKesson

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# Sunmark<sup>®</sup> children's loratadine syrup

**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

#### Questions?

Call 1-866-923-4914

Distributed by McKesson One Post Street, San Francisco, CA 94104

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

#### sunmark®

COMPARE TO CHILDREN'S CLARITIN<sup>®</sup> ACTIVE INGREDIENT\*

NDC 49348 849-34

24 HOUR ALLERGY RELIEF

children's loratadine syrup

(Loratadine Oral Solution) 5 mg/5 mL Antihis tamine

Relief of sneezing, runny nose itchy, watery eyes itchy throat or nose

Dye Free Non-drowsy† Ages two years & older

#### **GRAPE FLAVOR**

4 FL OZ (120 mL)

**†** When taken as directed. See Drug Facts Panel.



# SUNMARK CHILDRENS LORATADINE

loratadine solution

#### **Product Information**

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:49348-849

Active Ingredient/	Active Moiety					
			Basis	is of Strength Strength		
Loratadine (UNII: 7AJO	AJO3BO7QN) (Loratadine - UNII:7AJO3BO7QN) Lorata			dine 5 mg in 5 mL		
Inactive Ingredien	ts					
Ingredient Name					Strength	
citric acid monohydrat	itric acid monohydrate (UNII: 2968PHW8QP)				U	
glycerin (UNII: PDC6A30						
propylene glycol (UNII: 6DC9Q167V3)						
water (UNII: 059QF0KO						
sodium benzoate (UNII: OJ245FE5EU)						
sodium metabisulfite (UNII: 4VON5FNS3C)						
sucrose (UNII: C151H8M5	554)					
<b>Product Character</b>	ristics					
Color YEI	LLOW (colorless to slightly yellow)		S	core		
Shape			S	ize		
Flavor GR.	GRAPE			Imprint Code		
Contains						
Packaging						
# Item Code	Package Description	Marketin	ng Start Date	Mar	rketing End Date	
1 NDC:49348-849-34	1 in 1 CARTON					
1	120 mL in 1 BOTTLE					
Marketing Information						
Marketing Category	Application Number or Monogr	Application Number or Monograph Citation Marketin		art Date	Marketing End Date	
ANDA	ANDA076805		08/20/2004			

Labeler - McKesson (177667227)

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

# Establishment

Name	Address	ID/FEI	<b>Business Operations</b>
Taro Pharmaceutical Industries Ltd.		600072078	MANUFACTURE(49348-849)