

SUNMARK CHILDRENS LORATADINE SRP SF GRAPE- loratadine solution
Strategic Sourcing Services LLC

SUNMARK® CHILDREN'S LORATADINE SRP SF GRAPE

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	2 teaspoonfuls (tsp) daily; do not take more than 2
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children 6 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 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

butylated hydroxyanisole, glycerin, grape flavor, maltitol solution, masking agent, phosphoric acid, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium phosphate monobasic dihydrate, sorbitol solution, sucralose powder.

Questions?

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

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

PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

sunmark®

Original
Prescription
Strength

COMPARE TO
CHILDREN'S CLARITIN®
ACTIVE INGREDIENT*

NDC 70677-0029-1

children's
Allergy
Loratadine Oral Solution
USP, 5 mg/5 mL
(Antihistamine) ALLERGY

Non-Drowsy †

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

Indoor & Outdoor Allergies
Ages 2 years and older

Dye Free

Dosage Cup Enclosed

SUGAR FREE
GRAPE FLAVOR

4 FL OZ (120 mL)

†When taken as directed. See Drug Facts Panel.



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17

NO VARNISH/ NO AQ
NO COPY / NO COLOR
THIS FLAP FOR LOT #
AND EXP DATE PRINT



T181C
B98.2
ENG19.59

SUNMARK CHILDRENS LORATADINE SRP SF GRAPE
loratadine solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70677-0029
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		
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)				
GLYCERIN (UNII: PDC6A3C0OX)				
SORBITOL (UNII: 506T60A25R)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
PHOSPHORIC ACID (UNII: E4GA8884NN)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SODIUM PHOSPHATE, MONOBASIC, DIHYDRATE (UNII: 5QWK665956)				
Product Characteristics				
Color	yellow (colorless to slightly yellow)	Score		
Shape		Size		
Flavor	GRAPE (sugar free)	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70677-0029-1	1 in 1 CARTON	03/17/2017	
1		120 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	03/17/2017		

Labeler - Strategic Sourcing Services LLC (116956644)

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	manufacture(70677-0029)