SUNMARK CHILDRENS LORATADINE- loratadine solution Strategic Sourcing Services LLC

Sunmark[®] 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

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

 $sunmark^{\mathbb{R}}$

COMPARE TO CHILDREN'S CLARITIN® ACTIVE INGREDIENT*

NDC 49348-636-34

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-drows y†

Ages two years & older

FRUIT 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:49348-636
Route of Administration	ORAL		

l	Active Ingredient/Active Moiety		
ı	Ingredient Name	Basis of Strength	Strength
ı	Loratadine (UNII: 7AJO3BO7QN) (Loratadine - UNII:7AJO3BO7QN)	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	FRUIT	Imprint Code
Contains		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:49348-636-34	1 in 1 CARTON	11/14/2012	
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	08/20/2004	

Labeler - Strategic Sourcing Services LLC (116956644)

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

Establishment				
Name	Address	ID/FEI	Business Operations	
Taro Pharmaceutical Industries Ltd.		600072078	MANUFACTURE(49348-636)	

Revised: 11/2019 Strategic Sourcing Services LLC