CHILDRENS LORATADINE- loratadine solution
Pharmaceutical Associates, Inc.

Children's Loratadine Oral Solution

Drug Facts

Active ingredient (in each 5 mL (teaspoonful) (TSP))

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 older	2 teaspoonfuls (TSP) daily; do not take more than 2 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

- **Each teaspoonful (TSP) contains:** sodium 1 mg
- Store between 20° to 25°C (68° to 77°F)

Children's Loratadine Oral Solution is a clear, grape flavored solution supplied in the following oral dosage form:

NDC 0121-0849-10:	10 mL unit dose cup.
NDC 0121-0849-40:	Case contains 40 unit dose cups of 10 mL (0121-0849-10) packaged in 4 trays of 10 unit dose cups each.

Inactive ingredients

Butylated hydroxyanisole, citric acid, glycerin, grape flavor, propylene glycol, purified water, sodium benzoate, sucralose.

Questions

Call 1-800-845-8210

MANUFACTURED BY
Silarx Pharmaceuticals, Inc.
1033 Stoneleigh Ave
Carmel, NY 10512

PRINCIPAL DISPLAY PANEL - 10 mL Cup Tray Label

NDC 0121-0849-10

Children's Loratadine
Oral Solution

Dye Free/ Alcohol Free/ Sugar Free

10 mg/ 10 mL

USUAL DOSAGE: See attached Drug Facts

This unit-dose package is not child-resistant.

Store at 20° to 25°C (68° to 77°F)
[See USP Controlled Room Temperature].

10 x 10 mL Unit-Dose Cups

Pharmaceutical
Associates, Inc.
Greenville, SC 29605

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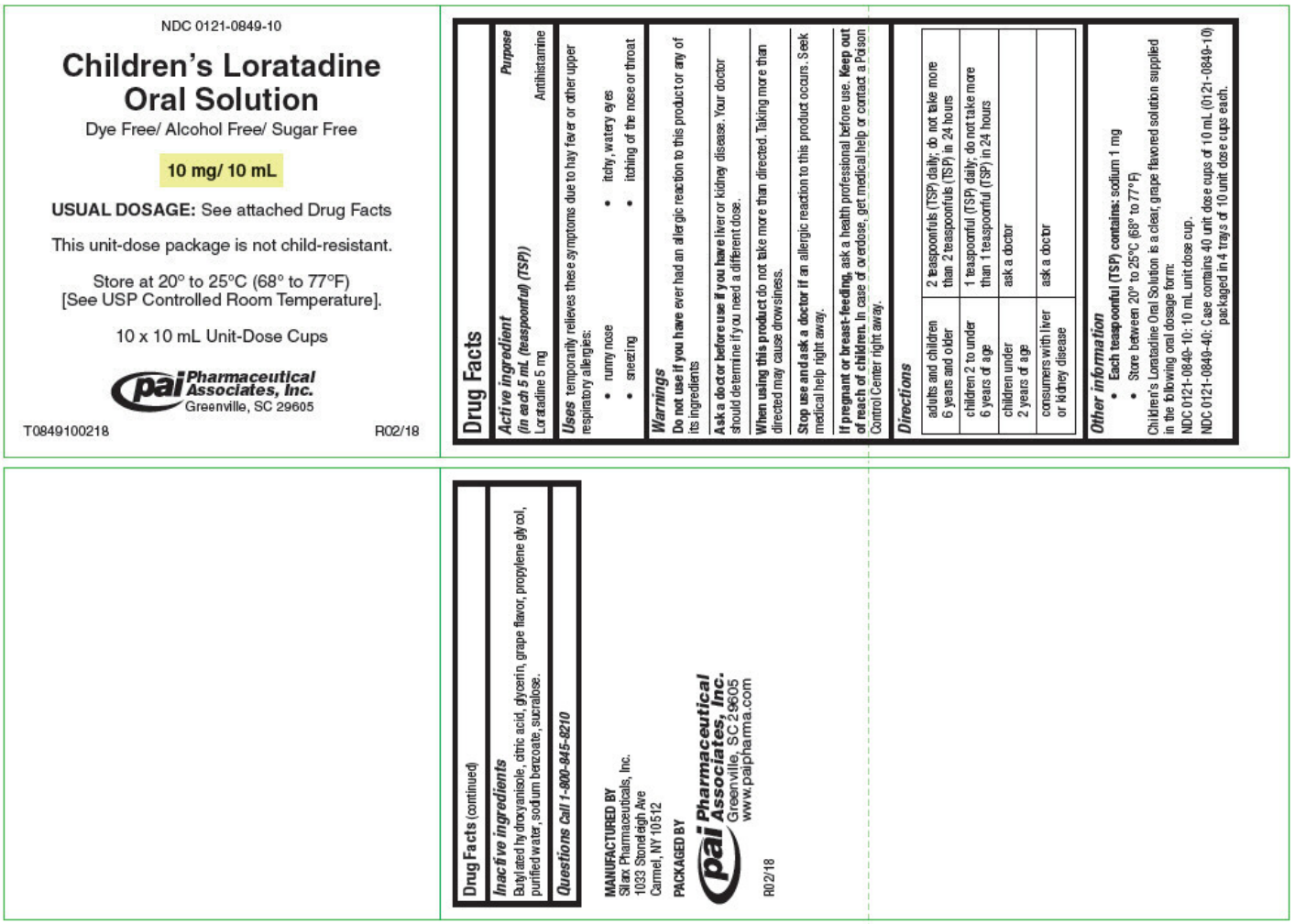
R02/18



CHILDRENS LORATADINE

loratadine solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0121-0849(NDC:54838-554)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN)	LORATADINE	5 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

WATER (UNII: 059QF0KO0R)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	GRAPE (grape flavor)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0121-0849-40	4 in 1 CASE	05/28/2018	
1		10 in 1 TRAY		
1	NDC:0121-0849-10	10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077421	11/24/2010	

Labeler - Pharmaceutical Associates, Inc. (044940096)

Establishment

Name	Address	ID/FEI	Business Operations
Pharmaceutical Associates, Inc.		097630693	repack(0121-0849)

Establishment

Name	Address	ID/FEI	Business Operations
Lannett Company, Inc.		161630033	label(0121-0849)

Revised: 5/2018 Pharmaceutical Associates, Inc.