CHILDRENS LORATADINE- loratadine solution Preferred Pharmaceuticals Inc.

Children's Loratadine

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

2 teaspoonfuls (tsp) daily; do

adults and children 6 years and over	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

- 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

artificial peach flavor, citric acid monohydrate, glycerin, propylene glycol, purified water, sodium benzoate, sodium metabisulfite, sucrose

Questions?

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

Distributed by: **Taro Pharmaceuticals U.S.A., Inc.** Hawthorne, NY 10532

Relabeled By: Preferred Pharmaceuticals Inc.

PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

NDC 68788-8266-1

Compare to the active ingredient in Children's Claritin®*

Original Prescription Strength

Children's Loratadine Oral Solution USP, 5 mg/5 mL

(Antihistamine)

24 Hour Relief of:

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose

Indoor & Outdoor Allergies

Ages 2 years and older

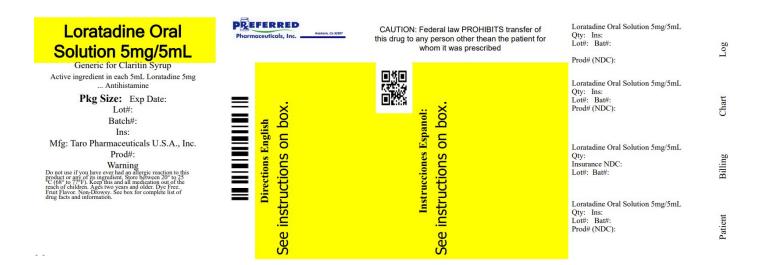
WARNING: Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions.

Dye Free Fruit Flavor

Dosage Cup Enclosed

[†]When taken as directed. See Drug Facts Panel.

4 FL OZ (120 mL)



CHILDRENS LORATADINE loratadine solution						
Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68788-8266(NDC:51672-2073)			
Route of Administration	ORAL					

Active Ingred	ient/Active Moiety			
	Ingredient Name	Basis of Stren	gth Strength	
Loratadine (UNII:	7AJO3BO7QN) (Loratadine - UNII:7AJO3BO7QN)	Loratadine	5 mg in 5 ml	
Inactive Ingre	edients			
	Ingredient Name		Strength	
citric acid monoh	ydrate (UNII: 2968PHW8QP)			
glycerin (UNII: PDC	C6A3C0OX)			
propylene glycol	(UNII: 6DC9Q167V3)			
water (UNII: 059QF	FOKOOR)			
	(UNII: OJ245FE5EU)			
	Ifite (UNII: 4VON5FNS3C)			
sucrose (UNII: C15	1H8M554)			
Product Char	acteristics			
Color	YELLOW (colorless to slightly yellow) Score			
Shape		Size	Size	
Flavor	FRUIT (peach)	Imprint C	Imprint Code	
Contains				
Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing Enc Date	
1 NDC:68788- 8266-1	1 in 1 CARTON	09/23/2022		
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	09/23/2022		

Labeler - Preferred Pharmaceuticals Inc. (791119022)

Registrant - Preferred Pharmaceuticals Inc. (791119022)

Establishment							
Name	Address	ID/FEI	Business Operations				
Preferred Pharmaceuticals Inc.		791119022	RELABEL(68788-8266)				