CHILDRENS LORATADINE ORAL- loratadine solution
PINNACLE PHARMA LLC

Major Pharmaceuticals Children’s Loratadine Oral Solution 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 and over	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

- do not use if carton is opened, or if printed neckband is broken or missing
- store between 20° to 25°C (68° to 77°F)

Inactive ingredients

edetate disodium, glycerin, maltitol, monobasic sodium phosphate, natural and artificial grape flavor, phosphoric acid, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose

Questions or comments?

1-800-616-2471

Package/Label Principal Display Panel

Compare to the active ingredient in Children’s Claritin®

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

(Antihistamine)

ALLERGY

Non-Drowsy†

Indoor & Outdoor Allergies

SUGAR FREE

Dye Free

24 Hour Relief of:

Sneezing

Runny Nose

Itchy, Watery Eyes

Itchy Throat or Nose

Ages 2 years and older

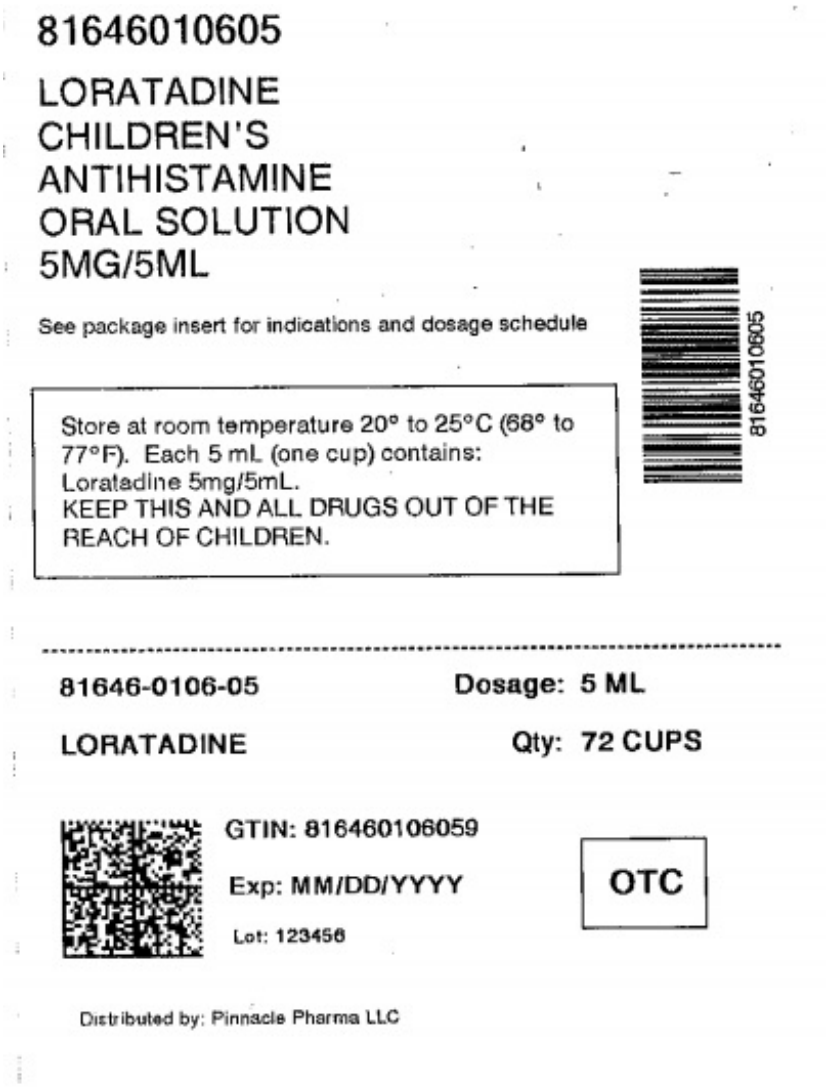
Dosing Cup Enclosed

Grape Flavor

†When taken as directed.

See Drug Facts Panel.

4 FL OZ (120 mL)



Loratidine case

Loratidine Label

CHILDRENS LORATADINE ORAL

loratadine solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:81646-106(NDC:0904-6767)
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**
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
MALTITOL (UNII: D65DG142WK)	
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81646-106-05	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product	02/12/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075728	02/12/2019	

Labeler - PINNACLE PHARMA LLC (081126970)

Revised: 4/2021

PINNACLE PHARMA LLC