

CHILDRENS LORATADINE ORAL- loratadine solution

Major Pharmaceuticals

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?

1-800-719-9260

Package/Label Principal Display Panel

MAJOR[®]

compare to the active ingredient in Children's Claritin[®]

children's loratadine oral solution

loratadine oral solution USP, 5 mg/5 mL

antihistamine

allergy

indoor & outdoor allergies

non-drowsy*

24-hour relief of:

- sneezing
- runny nose
- itchy, watery eyes

- itchy throat or nose

dye-free

sugar-free

ages 2 years and older

*when taken as directed. See drug facts panel.

grape flavor

dosing cup included

4 fl oz (120 mL)



CHILDRENS LORATADINE ORAL

loratadine solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-6767
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
LORATADINE (UNII: 7AJ03B07QN) (LORATADINE - UNII: 7AJ03B07QN)	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: 3980JH2SW)	
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:0904-6767-20	1 in 1 CARTON	02/12/2019	
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	ANDA075728	02/12/2019	

Labeler - Major Pharmaceuticals (191427277)