

## **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?

**1-800-616-2471**

### 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)



## CHILDRENS LORATADINE ORAL

loratadine solution

### Product Information

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

<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
LORATADINE (UNII: 7AJ03BO7QN) (LORATADINE - UNII:7AJ03BO7QN)		LORATADINE	5 mg in 5 mL	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>		<b>Strength</b>		
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)				
<b>Product Characteristics</b>				
<b>Color</b>		<b>Score</b>		
<b>Shape</b>		<b>Size</b>		
<b>Flavor</b>	GRAPE	<b>Imprint Code</b>		
<b>Contains</b>				
<b>Packaging</b>				
#	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		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA075728	02/12/2019		

**Labeler** - Major Pharmaceuticals (191427277)

Revised: 8/2020

Major Pharmaceuticals