# CHILDRENS LORATADINE ORAL- loratadine solution Major Pharmaceuticals

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#### 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)





in Children's Claritin<sup>a</sup>

(Antihistamine) ALLERGY Non-Drowsyt

**Indoor & Outdoor Allergies** 

#### SUGAR FREE

Dye Free

NDC 0904-6767-20

**MAJOR**°

**24**Hour Relief of:

- Runny Nose

Dosing Cup

- Itchy, Watery Eyes
  Itchy Throat or Nose

Ages 2 years and older

**Grape** Flavor %

4 FL OZ

 $(120 \,\mathrm{mL})$ 

†When taken as directed. See Drug Facts Panel.

4 FL OZ (120 mL)

Drug Facts Active ingredient (in each 5 mL teaspoonful)

active ingredient in Children's Garitin<sup>6</sup> compare to the

Purpose

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

lndoor & Outdoor Allergies Mon-Drowsy† When taken as directed See Drug Facts Panel. (An tih istamine) ALLERGY շթ, 5 mg/5 mL Oral Solution, Loratadine Children's

Warnings
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#### Directions

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Questions or comments? 1-800-616-2471

## **MAJOR**° Children's Loratadine **Oral Solution,** USP, 5 mg/5 mL

(Antihistamine) ALLERGY Non-Drowsy†

#### **Indoor & Outdoor Allergies**

- Dye-Free
- Sugar-Free
- 24 Hour Relief
- Alcohol-Free



<sup>†</sup>When taken as directed. See Drug Facts Panel.

\*This product is not manufactured or distributed by Bayer HealthCare LLC, distributor of Children's Claritin®. **Gluten Free** 

Retain Carton for Complete Product Information.

Distributed by: MAJOR® PHARMACEUTICALS 17177 N Laurel Park Drive, Suite 233 Livonia, MI 48152 M-05 REV. 09/18 Re-Order No. 700967



Ages 2 years and older

Grape

Flavor %

†When taken as directed. See Drug Facts Panel.



#### 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: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN)	LORATADINE	5 mg in 5 mL	

Inactive Ingredients	
Ingredient Name	Strength
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
MALTITOL (UNII: D65DG142WK)	
SO DIUM PHO SPHATE, MO NO BASIC, UNSPECIFIED FORM (UNII: 3980 JIH2S W)	
PHO SPHO RIC 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	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1 NDC:0904-6767-2	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)

Revised: 8/2020 Major Pharmaceuticals