

# CHILDRENS LORATADINE- loratadine tablet, chewable SAFEWAY

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**CHILDREN'S LORATADINE**

## ***Drug Facts***

### **Active ingredient (in each chewable tablet)**

Loratadine USP, 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**

- chew or crush tablets completely before swallowing.

adults and children 6 years and over	chew 2 tablets daily; not more than 2 chewable
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years and over	tablets in 24 hours
children 2 to under 6 years of age	chew 1 tablet daily; not more than 1 chewable tablet in 24 hours
children under 2 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

### Other information

- phenylketonurics: contains phenylalanine 1.25 mg per tablet.
- **TAMPER EVIDENT: DO NOT USE IF BLISTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING.**
- store between 20° to 25°C (68° to 77°F).

### Inactive ingredients

aspartame, citric acid anhydrous, colloidal silicon dioxide, D&C red No. 27 aluminum lake, FD&C blue No. 2 aluminum lake, flavor, magnesium stearate, mannitol, microcrystalline cellulose, sodium starch glycolate, stearic acid

### Questions?

call toll-free Monday to Friday 8:30 am to 5:00 pm EST at **1-800-406-7984**.

DISTRIBUTED BY  
 BETTER LIVING BRANDS LLC  
 P.O. BOX 99, PLEASANTON, CA  
 94566-0009

### PRINCIPAL DISPLAY PANEL - 5 mg Tablet Blister Pack Carton

Signature  
 care™  
 Quality  
 Guaranteed

Compare to  
 Children's Claritin® Chewables  
 active ingredient †

NDC 21130-963-20

24 Hour | Non-Drowsy\*

Children's Allergy Relief

AGES 2+ YEARS

LORATADINE CHEWABLE TABLETS USP, 5 mg Antihistamine

## GRAPE FLAVOR

### Actual Size

- Indoor & outdoor allergies
- Relief of: Sneezing; runny nose; itchy, watery eyes; itchy throat or nose

\*When taken as directed. See Drug Facts Panel.

The chewable tablets are to be chewed before swallowing.

20 CHEWABLE  
TABLETS



24 Hour | Non-Drowsy\*

# Children's Allergy Relief

AGES 2+ YEARS

LORATADINE CHEWABLE TABLETS USP, 5 mg Antihistamine



Compare to Children's Claritin® Chewables active ingredient\*

NDC 21130-963-20

24 Hour | Non-Drowsy\*

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DYE FREE | GRAPE FLAVOR



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20 CHEWABLE TABLETS

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\*All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Children's Claritin® Chewables.

Non Varnish Area

Batch No.

Expiration Date:

DISTRIBUTED BY:  
BETTER LIVING BRANDS LLC  
P.O. BOX 99  
PLEASANTON, CA 94566-0009  
†1-888-723-3929



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### Drug Facts

**Active ingredient (in each chewable tablet)** Purpose  
Loratadine USP, 5 mg ..... 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

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### Drug Facts (continued)

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Keep the carton. It contains important information. See end panel for expiration date.



5247754



5247754

GLUE - NO COATING

## CHILDRENS LORATADINE

loratadine tablet, chewable

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:21130-963
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
LORATADINE (UNII: 7AJ03BO7QN) (LORATADINE - UNII: 7AJ03BO7QN)	LORATADINE	5 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
ASPARTAME (UNII: Z0H242BBR1)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

## Product Characteristics

<b>Color</b>	white (white to off-white)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	10mm
<b>Flavor</b>	GRAPE	<b>Imprint Code</b>	LC5
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-963-20	2 in 1 CARTON	03/15/2024	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA210088	03/15/2024	

**Labeler** - SAFEWAY (009137209)

**Registrant** - OHM LABORATORIES INC. (184769029)

**Establishment**

Name	Address	ID/FEI	Business Operations
Ohm Laboratories		184769029	manufacture(21130-963)

Revised: 3/2024

SAFEWAY