# CHILDRENS LORATADINE- loratadine tablet, chewable SAFEWAY

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#### CHILDREN'S LORATADINE

**Drug Facts** 

## Active ingredient (in each 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	chew 2 tablets daily; not more	
and over	than 2 tablets in 24 hours	
children 2 to under 6 years	chew 1 tablet daily; not more than	
of age	1 tablet in 24 hours	
children under 2 years of	ask a doctor	
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<sup>TM</sup>

Quality

Guaranteed

Compare to Children's Claritin® Chewables active ingredient<sup>†</sup>

NDC 21130-999-20

24 Hour | Non-Drowsy\*

Children's Allergy Relief

**AGES 2 YEARS & OLDER** 

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

The chewable tablets are to be chewed before swallowing.

20 CHEWABLE

**TABLETS** 

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



24 Hour | Non-Drowsy

# Children's Allergy Relief

AGES 2 YEARS & OLDER

LORATADINE CHEWABLE TABLETS USP, 5 mg **Antihistamine** 



All trademarks affiliated

With

Batch No.

Non Varnish Area

s are property of their in the makers/owners of

respective owners. This product Children's Claritin® Chewables.

100

Date

## Compare to

Children's Claritin® Chewables

active ingredient

NDC 21130-999-20

24 Hour | Non-Drowsy\*

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 Relief of: Sneezing; runny nose; itchy, watery eyes; itchy throat or nose 20 CHEWABLE

**TABLETS** 

**GUARANTEED %00L** 

**QUALITY & SATISFACTION** ONE PROMISE www.betterlivingbrandsLLC.com R0619

1-888-723-3929 6000-99916 P.O. BOX 99, PLEASANTON, CA BETTER LIVING BRANDS LLC VA DISTRIBUTED BY

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## Drug Facts (continued)

## Directions

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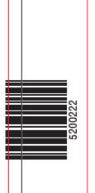
#### Inactive ingredients

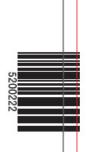
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Keep the carton. It contains important information. See end panel for expiration date.

GLUE - NO COATING





## **CHILDRENS LORATADINE**

loratadine tablet, chewable

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Product	Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:21130-999

Route of Administration ORAL

## **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN)	LORATADINE	5 mg

## **Inactive Ingredients**

3			
Ingredient Name	Strength		
aspartame (UNII: Z0H242BBR1)			
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)			
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)			
<b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)			
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)			
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**

Color	PURPLE (light purple to dark purple)	Score	no score
Shape	ROUND	Size	10 mm
Flavor	GRAPE	Imprint Code	753
Contains			

## **Packaging**

l	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1	NDC:21130-999-20	2 in 1 CARTON	07/01/2019	
ı	1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210088	07/01/2019	

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

Establishment				
Name	Address	ID/FEI	Business Operations	
Ohm Laboratories		184769029	MANUFACTURE(21130-999)	

Revised: 8/2019 SAFEWAY