

CHILDRENS LORATADINE- loratadine tablet, chewable SAFEWAY

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 and over	chew 2 tablets daily; not more than 2 tablets in 24 hours
children 2 to under 6 years of age	chew 1 tablet daily; not more than 1 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 21130-999-20

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

*When taken as directed. See Drug Facts Panel.

The chewable tablets are to be chewed before swallowing.

20 CHEWABLE
TABLETS



Quality Guaranteed

24 Hour | Non-Drowsy*

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Compare to Children's Claritin® Chewables active ingredient†

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RD 19176

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Scan here for more information.

Non Varnish Area

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

Batch No.

Expiration Date:

OUR PROMISE
100% GUARANTEED
QUALITY & SATISFACTION
OR YOUR MONEY BACK.

DISTRIBUTED BY
BETTER LIVING BRANDS LLC
P.O. BOX 99, PLEASANTON, CA
94566-0099
1-888-723-3929
www.betterlivingbrandsllc.com R0619

TAMPER EVIDENT: DO NOT
USE IF PACKAGE IS OPENED
OR IF BLISTER UNIT IS
TORN, BROKEN OR SHOWS
ANY SIGNS OF TAMPERING.

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Drug Facts (continued)

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

GLUE - NO COATING



5200222



5200222

CHILDRENS LORATADINE

loratadine tablet, chewable

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: 7AJ03BO7QN) (LORATADINE - UNII:7AJ03BO7QN)	LORATADINE	5 mg

Inactive Ingredients

Ingredient Name	Strength
aspartame (UNII: Z0H242BBR1)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
D&C RED NO. 27 (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	10mm
Flavor	GRAPE	Imprint Code	753
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-999-20	2 in 1 CARTON	07/01/2019	
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	

Labeler - SAFEWAY (009137209)

Registrant - OHMLABORATORIES INC. (184769029)

Establishment

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

Revised: 8/2019

SAFEWAY