

LORATADINE- loratadine tablet
Premier Value

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

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 **1-800-406-7984**

Distributed By:
Pharmacy Value Alliance, LLC
407 East Lancaster Avenue,
Wayne, PA 19087

PRINCIPAL DISPLAY PANEL - 5 mg Blister Pack Carton

†COMPARE TO THE ACTIVE
INGREDIENT OF CHILDREN'S
CLARITIN® CHEWABLES
NON-DROWSY*

Premier
Value®

Children's Loratadine Chewable
Tablets USP, 5 mg
Antihistamine

Indoor & Outdoor Allergies

Grape

ages 2 years
and older

24 Hour Relief of:

- Sneezing; Runny Nose; Itchy, Watery Eyes,
Itchy Throat or Nose

30 Chewable Tablets

The chewable tablets are to be chewed before swallowing.

*When taken as directed. See Drug Facts Panel.

**INDEPENDENTLY TESTED
SATISFACTION GUARANTEED**

If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.



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*COMPARE TO THE ACTIVE
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Indoor & Outdoor Allergies

24 Hour Relief of:

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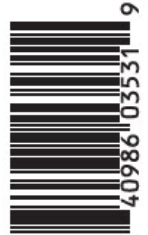
Grape



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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:



Children's Loratadine Chewable Tablets USP, 5 mg Antihistamine

Indoor & Outdoor Allergies



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Drug Facts (continued)

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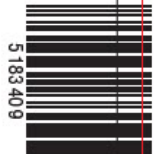
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Keep the carton. It contains important information. See end panel for expiration date.

GLUE - NO COATING



LORATADINE

loratadine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-053
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

Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
D&C red No. 27 aluminum lake (UNII: ZK64F7XSTX)	
FD&C BLUE NO. 2--ALUMINUM LAKE (UNII: 4AQJ3LG584)	
magnesium stearate (UNII: 70097M6B0)	
mannitol (UNII: 3OWL53L36A)	
microcrystalline cellulose (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
stearic acid (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	PURPLE (light to medium purple with a slightly speckled appearance)	Score	no score
Shape	ROUND (Flat face, beveled edge)	Size	10mm
Flavor	GRAPE	Imprint Code	753
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-053-10	1 in 1 CARTON	04/01/2018	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:68016-053-30	1 in 1 CARTON	04/01/2018	
2		30 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	04/01/2018	

Labeler - Premier Value (101668460)

Registrant - Ohm Laboratories (184769029)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	MANUFACTURE(68016-053)

Revised: 12/2019

Premier Value