# LORATADINE- loratadine tablet, chewable PUBLIX SUPER MARKETS INC

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

### 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

DISTRIBUTED BY PUBLIX SUPER MARKETS, INC., 3300 PUBLIX CORPORATE PARKWAY LAKELAND, FL 33811

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

NDC 56062-990-20

FOR AGES 2 YEARS AND OLDER INDOOR & OUTDOOR ALLERGIES

children's allergy

LORATADINE CHEWABLE TABLETS USP, 5 mg

**ANTIHISTAMINE** 

Non-drowsy\* 24-hour relief of:

- Sneezing Runny nose
- Itchy, watery eyes Itchy throat or nose

ACTUAL

SIZE

20

**CHEWABLE** 

**TABLETS** 

The chewable tablets are to be chewed before swallowing.

**GRAPE FLAVORED** 

\*When taken as directed. See Drug Facts Panel

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

### Keep the carbon. It contains important information. See end panel for expiration date. to this product occurs. Seek medical help right away. Stop use and ask a doctor if an allergic reaction stearate, pregelatinized starch corn starch, lactose monohydrate, magnesium directed. Taking more than directed may cause sinsibergni evitorni When using this product do not take more than TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING. ■ TAMPER EVIDENT: DO NOT USE IF BLISTER UNITS ARE disease. Your doctor should determine if you need a ■ bioject (tom excessive moisture Ask a doctor before use it you have liver or kidney ■ stone between 68° to 77° F (20° to 25° C) to this product or any of its ingredients. Other Information Do not use if you have ever had an allergic reaction spnin16W kidney disease век в достог consumers with liver or ■ Aching of the nose or throat sak a doctor cyliqueu nuger 6 years of age Buizeeus ■ ■ усру, марелу еуез stuod \$2 ni feldst 1 nedt and over eeou √uunu ■ 1 tablet daily; not more eqnits and children 6 years or other upper respiratory allergies: Directions temporarily relieves these symptoms due to hay fever right away (1-800-222-1222). get medical help or contact a Poison Control Center

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Purpose



perore use.



NDC 56062-526-69

Loratadine, USP 10 mg.

Active ingredient

(in each tablet)

Drug Facts

INDOOR & OUTDOOR ALLERGIES 24-HOUR

# allergyrelief

LORATADINE TABLETS, USP 10 mg

ANTIHISTAMINE

### Non-drowsy\* Relief of:

- Sneezing Runny nose
- Itchy, watery eyes
- Itchy throat or nose

TABLETS

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

Keep out of reach of children, in case of overdose,

If pregnant or breast-feeding, ask a health professional

Drug Facts (continued)



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LO

Batch No.

ACTUAL SIZE

\*Compare to the active ingredient of Claritin®

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Publix

### LORATADINE

loratadine tablet, chewable

## **Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56062-990
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)			
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)			
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)			
<b>D&amp;C RED NO. 27</b> (UNII: 2LRS 185U6K)			
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
MANNITOL (UNII: 30WL53L36A)			
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)			

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

Packaging			
# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1 NDC:56062-990- 20	2 in 1 CARTON	07/31/2019	
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	07/31/2019	

# Labeler - Publix Supermarkets Inc (006922009)

Establishment			
Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	MANUFACTURE(56062-990)

Revised: 8/2019 PUBLIX SUPER MARKETS INC