

**DYE-FREE CHILDRENS LORATADINE- loratadine tablet, chewable
PUBLIX SUPER MARKETS, INC**

Dye-Free Children's Loratadine Chewable Tablets USP, 5 mg

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

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 68° to 77°F (20° to 25°C).

Inactive ingredients

aspartame, citric acid anhydrous, colloidal silicon dioxide, 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 56062-921-20

FOR AGES 2+ YEARS
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

DYE FREE

ACTUAL
SIZE

20
CHEWABLE
TABLETS

GRAPE FLAVORED

*When taken as directed. See Drug Facts Panel

†Compare to the active ingredient
of Children's Claritin[®] Chewables



FOR AGES 2+ YEARS
INDOOR & OUTDOOR ALLERGIES

children'sallergy

LORATADINE CHEWABLE TABLETS USP, 5 mg
ANTIHISTAMINE



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ANTIHISTAMINE

Non-drowsy*

24-hour relief of:

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

DYE FREE

20 CHEWABLE TABLETS

The chewable tablets are to be chewed before swallowing.

*When taken as directed. See Drug Facts Panel.

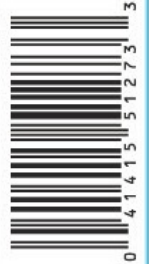


ACTUAL SIZE

GRAPE FLAVORED

*Compare to the active ingredient of Children's Claritin® Chewables

1023



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PUBLIX GUARANTEE: COMPLETE SATISFACTION OR YOUR MONEY BACK

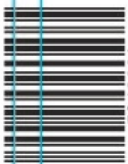
publix.

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: _____

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

<p>Drug Facts Active ingredient (in each chewable tablet) Loratadine USP, 5 mg Antihistamine</p>	
<p>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</p>	
<p>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).</p>	
<p>Other information ■ phenylethanolamine 1.25 mg per tablet ■ contains phenylethanolamine 1.25 mg per tablet TAMPER EVIDENT: DO NOT USE IF BLISTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING. ■ store between 68° to 77°F (20° to 25°C).</p>	
<p>Inactive ingredients aspartame, citric acid anhydrous, colloidal silicon dioxide, flavor, magnesium stearate, mannitol, microcrystalline cellulose, sodium starch glycolate, stearic acid</p>	
<p>Questions? call toll-free Monday to Friday 8:30 am to 5:00 pm EST at 1-800-406-7984.</p>	
<p>Drug Facts (continued)</p>	
<p>Directions ■ chew or crush tablets completely before swallowing.</p>	<p>Purpose Antihistamine</p>
<p>adults and children chew 2 tablets daily; not more than 2 chewable tablets in 24 hours</p>	<p>6 years and over chew 2 chewable tablets in 24 hours</p>
<p>children 2 to under 6 years of age chew 1 chewable tablet in 24 hours</p>	<p>children under 2 years of age ask a doctor</p>
<p>consumers with liver or kidney disease ask a doctor</p>	<p>ask a doctor</p>



6906425



5249039

GLUE - NO COATING

DYE-FREE CHILDRENS LORATADINE

loratadine tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56062-921
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)	
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	white (white to off-white)	Score	no score
Shape	ROUND (bevelled edge)	Size	10mm
Flavor	GRAPE	Imprint Code	LC5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062-921-20	2 in 1 CARTON	03/15/2024	
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	03/15/2024	

Labeler - PUBLIX SUPER MARKETS, INC (006922009)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(56062-921)

Revised: 3/2024

PUBLIX SUPER MARKETS, INC