

LORATADINE- loratadine tablet, chewable
PUBLIX SUPER MARKETS INC

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

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

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

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)	
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)	
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	10mm
Flavor	GRAPE	Imprint Code	753
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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 SUPER MARKET S INC (006922009)

Establishment

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

