

DYE-FREE CHILDRENS LORATADINE- loratadine tablet, chewable UP & UP

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 tablets in 24
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years and over	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 20° to 25°C (68° to 77°F).

Inactive ingredients

aspartame, citric acid anhydrous, colloidal silicon dioxide, 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 Target Corporation
Minneapolis, MN 55403

PRINCIPAL DISPLAY PANEL - 5 mg Tablet Blister Pack Carton

Compare to active ingredient in Children's
Claritin[®] Chewables*

NDC 11673-115-30

Ages 2+ years

dye-free
children's
allergy

loratadine chewable tablets USP, 5 mg
antihistamine

non-drowsy**
indoor and outdoor allergies
24-hour relief of:

- sneezing
- runny nose
- itchy, watery eyes
- itchy throat or nose

**When taken as directed. See drug facts panel.

up & up

BUBBLEGUM
FLAVOR

ACTUAL SIZE

30
CHEWABLE
TABLETS

30 CHEWABLE TABLETS

THE CHEWABLE TABLETS ARE
TO BE CHEWED BEFORE SWALLOWING



DYE-FREE CHILDRENS LORATADINE

loratadine tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11673-115
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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 (beveled edge)	Size	10mm	
Flavor	BUBBLE GUM	Imprint Code	112	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11673-115-30	3 in 1 CARTON	11/17/2020	
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		11/17/2020	

Labeler - UP & UP (006961700)

Establishment			
Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(11673-115)

