

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

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**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.

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adults and children 6 years and over | chew 2 tablets daily; not more than 2 chewable tablets in 24

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

NDC 11673-115-30

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

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

up&up

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

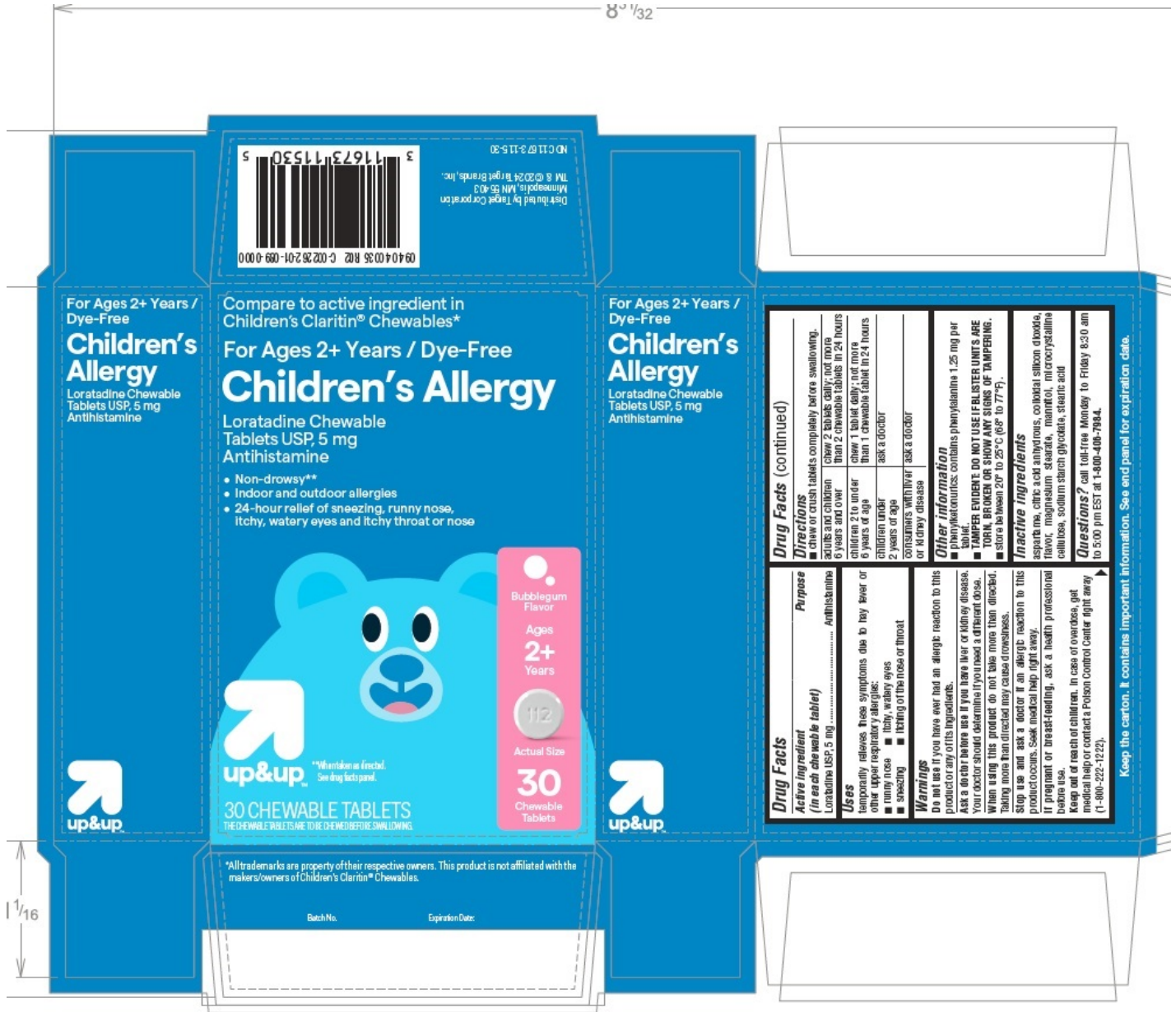
30 CHEWABLE TABLETS

THE CHEWABLE TABLETS ARE  
TO BE CHEWED BEFORE SWALLOWING

Bubblegum  
Flavor

Actual Size

30  
CHEWABLE  
TABLETS



<b>DYE-FREE CHILDRENS LORATADINE</b>			
loratadine tablet, chewable			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11673-115
<b>Route of Administration</b>	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)