

DYE-FREE CHILDRENS LORATADINE- loratadine tablet, chewable
Ohm Laboratories 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
- sneezing
- itchy, watery eyes
- 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 2 chewable tablets in
-----------------------------	---

and over	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 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**.

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

Distributed by:

Ohm Laboratories Inc.
New Brunswick, NJ 08901

0420

PRINCIPAL DISPLAY PANEL - 5 mg Tablet Blister Pack Carton

NDC 51660-726-30

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

Ages 2+ years

Children's

Loratadine Chewable Tablets USP, 5 mg

Antihistamine

Indoor & Outdoor Allergies

30 CHEWABLE TABLETS

The chewable tablets are to be chewed before swallowing.

Dye-Free

Grape Flavored

Non-Drowsy*

24 Hour Relief of:

- ***Sneezing***
- ***Runny Nose***
- ***Itchy, Watery Eyes***
- ***Itchy Throat or Nose***

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

†Ohm® is a registered trademark of Sun Pharmaceutical Industries, Inc. All other trademarks are property of their respective owners.

Children's
Loratadine Chewable
Tablets USP, 5 mg
Dye-Free
Grape
Flavored
30 CHEWABLE TABLETS
The chewable tablets are
to be chewed before swallowing.

ohm[®] NDC 51660-726-30
Ages 2+ years
Dye-Free
Grape
Flavored
Compare To
the active ingredient of
Children's Claritin[®]
Chewables
Children's
Loratadine Chewable
Tablets USP, 5 mg
Antihistamine
Indoor & Outdoor Allergies
Non-Drowsy*
24 Hour Relief of:
• Sneezing
• Runny Nose
• Itchy, Watery Eyes
• Itchy Throat or Nose
30 CHEWABLE TABLETS
The chewable tablets are to be chewed before swallowing. *When taken as directed. See Drug Facts Panel.

1223
Distributed by:
Ohm Laboratories Inc.
New Brunswick, NJ 08901
3 51660 172630 5

ohm[®] Dye-Free
Grape
Flavored
Children's
Loratadine Chewable
Tablets USP, 5 mg
Indoor & Outdoor Allergies
30 CHEWABLE TABLETS
The chewable tablets are
to be chewed before swallowing.

Drug Facts		Drug Facts (continued)	
Active ingredient (in each chewable tablet)	Purpose	Directions	
Loratadine USP, 5 mg	Antihistamine	chew or crush tablets completely before swallowing.	
Uses		adults and children 6 years and over	chew 2 tablets daily; not more than 2 chewable tablets in 24 hours
temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:		children 2 to under 6 years of age	chew 1 tablet daily; not more than 1 chewable tablet in 24 hours
<ul style="list-style-type: none"> ■ runny nose ■ itchy, watery eyes ■ sneezing ■ itching of the nose or throat 		children under 2 years of age	ask a doctor
Warnings		consumers with liver or kidney disease	ask a doctor
Do not use if you have ever had an allergic reaction to this product or any of its ingredients.		Other information	
Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.		<ul style="list-style-type: none"> ■ 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). 	
When using this product do not take more than directed. Taking more than directed may cause drowsiness.		Inactive ingredients	
Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.		aspartame, citric acid anhydrous, colloidal silicon dioxide, flavor, magnesium stearate, mannitol, microcrystalline cellulose, sodium starch glycolate, stearic acid	
If pregnant or breast-feeding, ask a health professional before use.		Questions? call toll-free Monday to Friday 8:30 am to 5:00 pm EST at 1-800-406-7984.	
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).			

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

5246146

GLUE - NO COATING

DYE-FREE CHILDRENS LORATADINE

loratadine tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51660-726
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:51660-726-30	3 in 1 CARTON	03/15/2024	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:51660-726-61	6 in 1 CARTON	10/18/2024	
2		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 - Ohm Laboratories Inc. (184769029)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(51660-726)

Revised: 3/2024

Ohm Laboratories Inc.