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 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 and	chew 2 tablets daily; not more than 2 tablets in 24 hours
over	
children 2 to under 6 years of	chew 1 tablet daily; not more than 1 tablet in 24 hours
age	
children under 2 years of age	ask a doctor
consumers with liver or kidney	ask a doctor
disease	

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 51660-106-31

[†]Compare to the active ingredient of Children's Claritin[®] Chewable ages 2 years and older

Children's

Loratadine Chewable Tablets USP, 5 mg

Antihis tamine

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

†Ohm® is a registered trademark of Sun Pharmaceutical Industries, Inc. All other trademarks

^{*}When taken as directed. See Drug Facts Panel.

are property of their respective owners.			



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GLUE - NO COATING

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before use.

(1-800-222-1222).

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medical help or contact a Poison Control Center right away

DYE-FREE CHILDRENS LORATADINE

loratadine tablet, chewable

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51660-106	
Route of Administration	ORAL			

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)		
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	10 mm	
Flavor	GRAPE	Imprint Code	106	
Contains				

	Packaging				
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
ı	1 NDC:51660-106-31	3 in 1 CARTON	09/01/2020		
l	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	09/01/2020	

Labeler - Ohm Laboratories Inc. (184769029)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	MANUFACTURE(51660-106)

Revised: 9/2020 Ohm Laboratories Inc.