LORATADINE- loratadine tablet, chewable
Ohm Laboratories Inc.

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 doctorbefore 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.

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° and 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

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

0619

Principal Display Panel – 30 Chewable Tablet Blister Pack Carton

NDC 51660-753-31

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

ages 2 years and older

Children's

Loratadine Chewable Tablets USP, 5 mg

Antihistamine

Indoor & Outdoor Allergies

30 CHEWABLE TABLETS

The chewable tablets are to be chewed before swallowing.

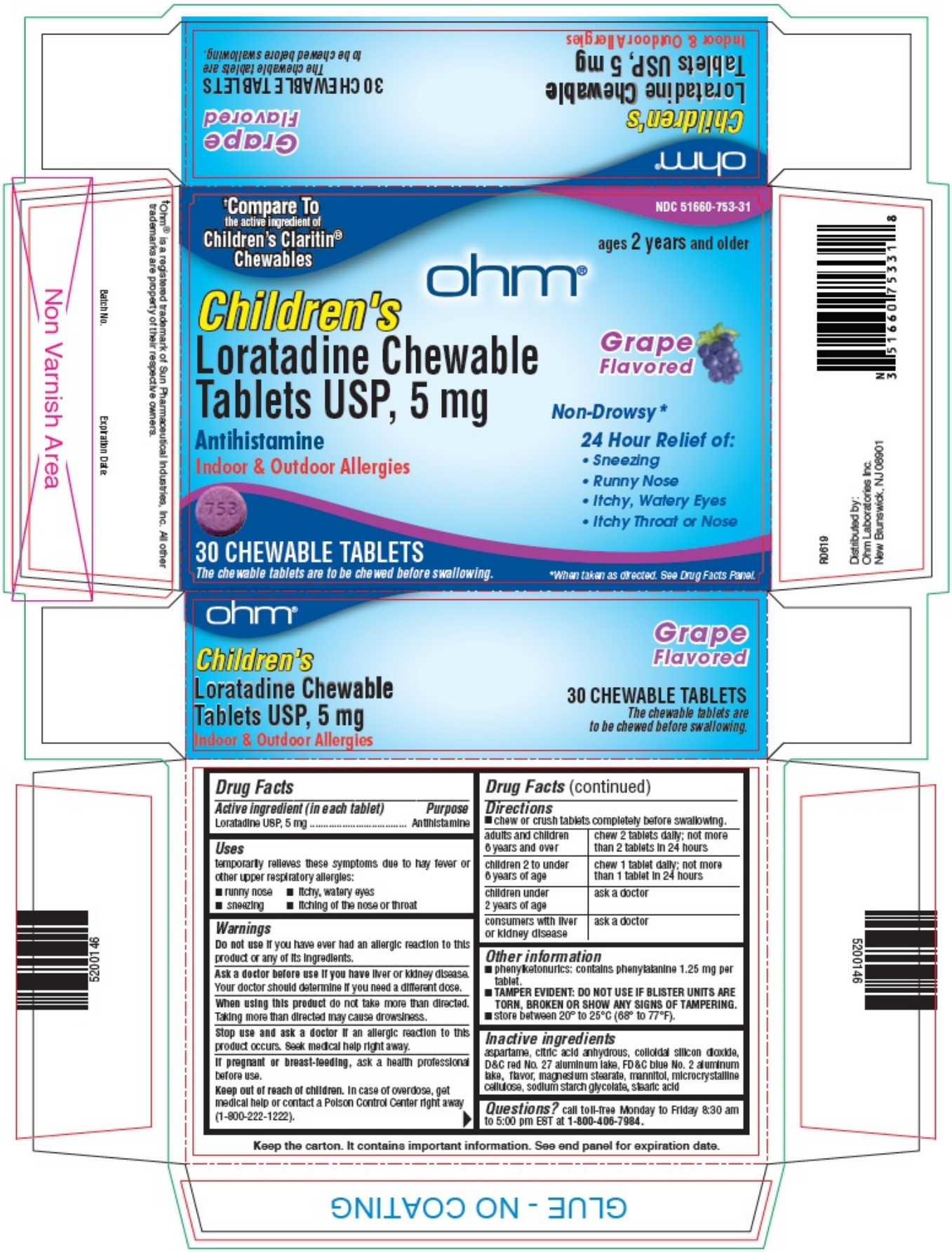
Grape Flavored

Non-Drowsy*

24 Hour Relief Of:

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

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


Children's
Loratadine Chewable
Tablets USP, 5 mg
Indoor & Outdoor Allergies
ohm
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24 Hour Relief of:
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753
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R0619
Distributed by:
Ohm Laboratories Inc.
New Brunswick, NJ 08901
Batch No.
Expiration Date
Non Varnish Area
*Ohm® is a registered trademark of Sun Pharmaceutical Industries, Inc. All other trademarks are property of their respective owners.
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Drug Facts (continued)
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GLUE - NO COATING

LORATADINE

loratadine tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51660-753
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:51660-753-31	3 in 1 CARTON	06/01/2018	
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	06/01/2018	

Labeler - Ohm Laboratories Inc. (184769029)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	MANUFACTURE(51660-753)