CHILDRENS LORATADINE- loratadine tablet, chewable TARGET CORPORATION

CHILDREN'S LORATADINE

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
- 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	chew 2 tablets daily; not more
6 years and over	than 2 tablets in 24 hours
children 2 to under	chew 1 tablet daily; not more
6 years of age	than 1 tablet in 24 hours
children under 2	ask a doctor
years of age	
consumers with	ask a doctor
liver or kidney	
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, carmine, citric acid anhydrous, colloidal silicon dioxide, flavor, magnesium stearate, mannitol, microcrystalline cellulose, sodium starch glycolate, stearic acid

Questions?

Call 1-800-910-6874

Distributed by Target Corporation Minneapolis, MN 55403

PRINCIPAL DISPLAY PANEL - 5 mg Tablet Blister Pack Carton

NDC 11673-997-30

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

children's

allergy

loratadine chewable tablets USP, 5 mg antihistamine

up&up

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.

30 CHEWABLE TABLETS

THE CHEWABLE TABLETS ARE TO BE CHEWED BEFORE SWALLOWING

BUBBLEGUM FLAVOR

ACTUAL SIZE

30

CHEWABLE

TABLETS



children's allergy

loratadine chewable tablets USP, 5 mg <u>antihista</u>mine

Compare to active ingredient in Children's Claritin® Chewables

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 eyesitchy throat or nose
- "When taken as directed. See drug facts panel.

30 CHEWABLE TABLETS THE PERSON REPORTS AND LOWING

NDC 11673-997-30



BUBBLEGUM FLAVOR



ACTUAL SIZE

CHEWABLE

R0619

100% satisfaction guaranteed or your money back.

094 04 0035 R00 C-000974-01-004



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Drug Facts

Active ingredient (in each tablet) Purpose Loratadine USP, 5 mg

Uses

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
 - itchy, watery eyes
- itching of the nose or throat

(1-800-222-1222).

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

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away

Drug Facts (continued)

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° to 77°F).

Inactive ingredients

aspartame, carmine, citric acid anhydrous, colloidal silicon dioxide, flavor, magnesium stearate, mannitol, microcrystalline cellulose, sodium starch glycolate, stearic acid

Questions? Call 1-800-910-6874

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

GLUE - NO COATING



Non Varnish Area

CHILDRENS LORATADINE

loratadine tablet, chewable

Product	Infor	matian
Product	THIO	amation

Route of Administration ORAL

Active Ingredient/Active Moiety

l	Ingredient Name	Basis of Strength	Strength
ı	LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN)	LORATADINE	5 mg

Inactive Ingredients Ingredient Name

Ingredient Name	Strength
aspartame (UNII: Z0H242BBR1)	
cochineal (UNII: TZ8Z31B35M)	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
magnesium stearate (UNII: 70097M6I30)	
A LATING COLUMN TO COLUMN	

mannitol (UNII: 3OWL53L36A) microcrystalline cellulose (UNII: OP1R32D61U)

SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)

stearic acid (UNII: 4ELV7Z65AP)

Product Characteristics

Color	plor pink (light to medium pink with a slightly speckled appearance) Score no score		
Shape	ROUND (Flat face, beveled edge)	Size	10 mm
Flavor	BUBBLE GUM	Imprint Code	754
Contains			

Contains

Packaging

ш	0 0			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:11673-997-30	3 in 1 CARTON	03/31/2019	
ı	1	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Mai keting inioi mation			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210088	03/31/2019	

Labeler - TARGET CORPORATION (006961700)

Registrant - Ohm Laboratories (051565745)

Establishment			
Name	Address	ID/FEI	Business Operations
Ohm Laboratories		184769029	MANUFACTURE(11673-997)

Revised: 8/2019 TARGET CORPORATION