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

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

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

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

NDC 11673-111-30

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

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

up & up

GRAPE

FLAVOR

ACTUAL SIZE

30

CHEWABLE

TABLETS

30 CHEWABLE TABLETS

THE CHEWABLE TABLETS ARE TO BE CHEWED BEFORE SWALLOWING



DYE-FREE CHILDRENS LORATADINE

Loratadine (UNII: 7AJO3BO7QN) (Loratadine - UNII:7AJO3BO7QN)

loratadine tablet, chewable

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:11673-111

Route of Administration ORAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength

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			
:	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:11673-111-30	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(11673-111)		

Revised: 11/2020 UP & UP