

**LORATADINE- loratadine tablet, orally disintegrating
CVS PHARMACY, INC**

Loratidine Orally Disintegrating Tablets, USP

Drug Facts

Active ingredient (in each tablet)

Loratadine 10 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.

Directions

- place 1 tablet on tongue; tablet disintegrates, with or without water

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

Other information

- safety sealed: do not use if the individual blister unit imprinted with Loratadine Orally Disintegrating Tablet, USP is open or torn
- store between 20° to 25°C (68° to 77°F)
- use tablet immediately after opening individual blister
- complies with USP Procedure 2 for Assay and Organic Impurities and Test 2 for Disintegration

Inactive ingredients

anhydrous citric acid, mannitol, peppermint flavor, polysorbate 80, pullulan

Questions or comments?

1-877-244-9825

Manufactured by:

Tenshi Kaizen Private Limited

Bengaluru Rural - 562112, India

Revised: 11/2020

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

CVS Health

Indoor & Outdoor Allergies

Children's

LORATADINE ORALLY

DISINTEGRATING

TABLETS USP, 10 mg

Antihistamine

Allergy Relief

Non-Drowsy*

Original Prescription Strength

24 hour relief of:

Sneezing; Runny nose; Itchy,
 watery eyes; Itchy throat or nose
 Ages 6 yrs & older

**30 ORALLY
 DISINTEGRATING
 TABLETS**

CVS Health. Compare to the active ingredient in Claritin® Juniors RediTabs®†
Indoor & Outdoor Allergies

Children's Allergy Relief
 LORATADINE ORALLY DISINTEGRATING TABLETS USP, 10 mg Antihistamine

24 HOUR

Non-Drowsy* Original Prescription Strength
24 hour relief of:
 Sneezing; Runny nose; Itchy, watery eyes; Itchy throat or nose
Ages 6 yrs & older

No Water Needed, Melts in Your Mouth

Actual Size

30 ORALLY DISINTEGRATING TABLETS

*When taken as directed. See Drug Facts Panel

Indoor & Outdoor Allergies

24 HOUR

Drug Facts (Continued)	Other Information	Inactive Ingredients:	Questions or comments?	Loratadine Orally Disintegrating Tablets USP, 10 mg
Active ingredient (in each tablet) Loratadine 10 mg.	Purpose Antihistamine	anhydrous citric acid, mannitol, peppermint flavor, poly sorbate 80, pullulan	• safety sealed: do not use if the individual blister unit imprinted with Loratadine Orally Disintegrating Tablets, USP is open or torn • store between 20° to 25°C (68° to 77°F) • use tablet immediately after opening individual blister • complies with USP Procedure 2 for Assay and Organic Impurities and Test 2 for Disintegration	• No Water Needed • Melts in Your Mouth
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.		• Our Medical Information center shall operate between 9:00 AM to 5:00 PM EST from Monday through Friday (business hours). Queries received outside business hours shall reach voice mail and shall be attended on next business day	Follow these directions carefully: Do not attempt to push the tablet through the foil. 1. Peel back outer edge. 2. Gently push tablet out. 3. Place the tablet on tongue and dissolve in mouth. The tablet will disintegrate.
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.			
DIRECTIONS: Place 1 tablet on tongue; tablet disintegrates, with or without water adults and children 6 years and over 1 tablet daily; not more than 1 tablet in 24 hours children under 6 years of age consumers with liver or kidney disease ask a doctor				

#650107

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Code No.:
 NRDRUESYKTK2506652017

CVS Quality
Money Back Guarantee

†This product is not manufactured or distributed by Bayer HealthCare LLC, distributor of Claritin® Juniors RediTabs®. Bayer HealthCare LLC is the owner of the registered trademark Claritin® Juniors RediTabs®.
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 Made in India V-37564

LORATADINE			
loratadine tablet, orally disintegrating			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51316-503

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LORATADINE (UNII: 7AJ03BO7QN) (LORATADINE - UNII:7AJ03BO7QN)	LORATADINE	10 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
PULLULAN (UNII: 8ZQ0AYU1TT)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
MANNITOL (UNII: 3OWL53L36A)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	12mm
Flavor	MINT	Imprint Code	T10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-503-02	2 in 1 CARTON	08/08/2021	
1		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:51316-503-03	3 in 1 CARTON	08/08/2021	
2		30 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:51316-503-05	5 in 1 CARTON	08/08/2021	
3		50 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:51316-503-06	6 in 1 CARTON	08/08/2021	
4		60 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:51316-503-04	4 in 1 CARTON	08/08/2021	
5		40 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:51316-503-01	1 in 1 CARTON	08/08/2021	
6		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	ANDA213294	08/08/2021	

Labeler - CVS PHARMACY, INC (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
Tenshi Kaizen Pvt Ltd		675478488	analysis(51316-503) , manufacture(51316-503) , pack(51316-503)

Revised: 1/2024

CVS PHARMACY, INC