

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

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**Loratadine Orally Disintegrating Tablets USP**

**Drug Facts**

**Active ingredient (in each tablet)**

Loratadine 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.

**Directions**

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

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adults and children 6 years and over	1 tablet every 12 hours; not more than 2 tablets in 24
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	hours
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** - 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.

Manufactured by:

#### **Tenshi Kaizen Private Limited**

Bengaluru Rural - 562112, India

Distributed by:

#### **CVS Pharmacy, Inc.**

Revised: 09/2020

### **PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**



## LORATADINE

loratadine tablet, orally disintegrating

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51316-502
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
LORATADINE (UNII: 7AJ03BO7QN) (LORATADINE - UNII:7AJ03BO7QN)	LORATADINE	5 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	PEPPERMINT	Imprint Code	T5
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-502-01	1 in 1 CARTON	12/31/2021	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:51316-502-02	2 in 1 CARTON	12/31/2021	
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:51316-502-03	3 in 1 CARTON	12/31/2021	
3		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:51316-502-04	4 in 1 CARTON	12/31/2021	
4		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:51316-502-05	5 in 1 CARTON	12/31/2021	
5		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:51316-502-06	6 in 1 CARTON	12/31/2021	
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
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ANDA	ANDA212795	12/31/2021	
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**Labeler - CVS PHARMACY, INC (062312574)**

**Establishment**

Name	Address	ID/FEI	Business Operations
Reed-Lane, Inc.		001819879	pack(51316-502)

**Establishment**

Name	Address	ID/FEI	Business Operations
Quality Packaging Specialists International, LLC		825078165	pack(51316-502)

**Establishment**

Name	Address	ID/FEI	Business Operations
Tenshi Kaizen Pvt Ltd		675478488	analysis(51316-502) , manufacture(51316-502) , pack(51316-502)

Revised: 12/2024

CVS PHARMACY, INC