

**LORATADINE- loratadine tablet, orally disintegrating**  
**Tenshi Kaizen Pvt Ltd**

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**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

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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: 01/2023

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

NDC 72983-501-01

### **Non-Drowsy\***

### **Loratadine Orally Disintegrating Tablets USP, 10 mg**

antihistamine

Indoor & Outdoor

### **Allergies**

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

### **24 Hour Relief of:**

*Sneezing*

*Runny Nose*

*Itchy, Watery Eyes*

*Itchy Throat or Nose*

No Water Needed  
 Melts in Your Mouth  
**10**  
**ORALLY**  
**DISINTEGRATING TABLETS**



## LORATADINE

loratadine tablet, orally disintegrating

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72983-501
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name		Basis of Strength	Strength	
LORATADINE (UNII: 7AJ03BO7QN) (LORATADINE - UNII:7AJ03BO7QN)		LORATADINE	10 mg	
<b>Inactive Ingredients</b>				
Ingredient Name		Strength		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
PULLULAN (UNII: 8ZQ0AYU1TT)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
MANNITOL (UNII: 3OWL53L36A)				
<b>Product Characteristics</b>				
Color	white	Score	no score	
Shape	ROUND	Size	12mm	
Flavor	MINT	Imprint Code	T10	
Contains				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72983-501-03	3 in 1 CARTON	05/19/2021	
1		30 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:72983-501-01	1 in 1 CARTON	05/19/2021	
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA213294	05/19/2021		

**Labeler** - Tenshi Kaizen Pvt Ltd (675478488)

### Establishment

Name	Address	ID/FEI	Business Operations
Tenshi Kaizen Pvt Ltd		675478488	analysis(72983-501) , manufacture(72983-501) , pack(72983-501)