

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

-----  
**Loratidine Orally Disintegrating Tablets, USP**  
**Mint Flavor**

***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
- sneezing
- itchy, watery eyes
- 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 use more than directed. Taking more than recommended 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 | 1 tablet daily; do not |
|-----------------------|------------------------|

|  |                                    |
|--|------------------------------------|
| adults and children 6 years and over       | use more than 1 tablet in 24 hours |
| children under 6 years of age              | ask a doctor                       |
| consumers who have liver or kidney disease | ask a doctor                       |

### Other information

- safety sealed: do not use if the individual blister unit printed with Loratadine orally disintegrating tablet is open or torn
- store at 20-25°C (68-77°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?

Call Toll-free weekdays 9 AM to 5 PM EST at 1-888-375-3784

Manufactured By: Tenshi Kaizen Private Limited

Bengaluru Rural - 562112, India

### PRINCIPAL DISPLAY PANEL - 10 mg Tablet Blister Pack Carton

NEW FORMULA

NON-DROWSY\*

ALLERGY RELIEF

Loratadine Orally Disintegrating Tablet USP, 10 mg  
Antihistamine

Indoor/Outdoor

ALLERGIES

24 Hour Relief of

Sneezing, Runny Nose

Itchy/Watery Eyes

Itchy Throat or Nose

Melts In Your Mouth

FRESH MINT Flavor

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

60 Orally Disintegrating Tablets



## LORATADINE

loratadine tablet, orally disintegrating

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:72983-503 |
| <b>Route of Administration</b> | ORAL           |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength |
|---|-------------------|----------|
| LORATADINE (UNII: 7AJ03B07QN) (LORATADINE - UNII: 7AJ03B07QN) | LORATADINE        | 10 mg    |

## Inactive Ingredients

| Ingredient Name                                 | Strength |
|---|----------|
| <b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL) |          |
| <b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)        |          |
| <b>MANNITOL</b> (UNII: 3OWL53L36A)              |          |
| <b>PULLULAN</b> (UNII: 8ZQ0AYU1TT)              |          |

## Product Characteristics

|                 |                             |                     |          |
|-----------------|-----------------------------|---------------------|----------|
| <b>Color</b>    | white (white to off- white) | <b>Score</b>        | no score |
| <b>Shape</b>    | ROUND                       | <b>Size</b>         | 12mm     |
| <b>Flavor</b>   | MINT                        | <b>Imprint Code</b> | M24      |
| <b>Contains</b> |                             |                     |          |

## Packaging

| # | Item Code        | Package Description                                    | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:72983-503-06 | 60 in 1 CARTON   | 05/07/2024           |                    |
| 1 |                  | 1 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                               | 05/07/2024           |                    |

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

## Establishment

| Name                  | Address | ID/FEI    | Business Operations  |
|-----------------------|---------|-----------|--|
| Tenshi Kaizen Pvt Ltd |         | 675478488 | analysis(72983-503) , manufacture(72983-503) , pack(72983-503) |

Revised: 5/2024

Tenshi Kaizen Pvt Ltd