LORATADINE- loratadine tablet
Tenshi Kaizen Pvt Ltd

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

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

	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

Revised: 01/2023

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

LORATADINE

loratadine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72983-500
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN)	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:72983-500-01	1 in 1 CARTON	05/19/2021	
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	ANDA212795	05/19/2021	

Labeler - Tenshi Kaizen Pvt Ltd (675478488)

Establishment

Name	Address	ID/FEI	Business Operations
Tenshi Kaizen Pvt Ltd		675478488	analysis(72983-500) , manufacture(72983-500) , pack(72983-500)

Revised: 1/2024 Tenshi Kaizen Pvt Ltd