LORATADINE- loratadine tablet, orally disintegrating
Strides Pharma 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

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

Distributed by:

Strides Pharma Inc.

East Brunswick,

NJ 08816

Revised: 11/2020

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 59556-917-01

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

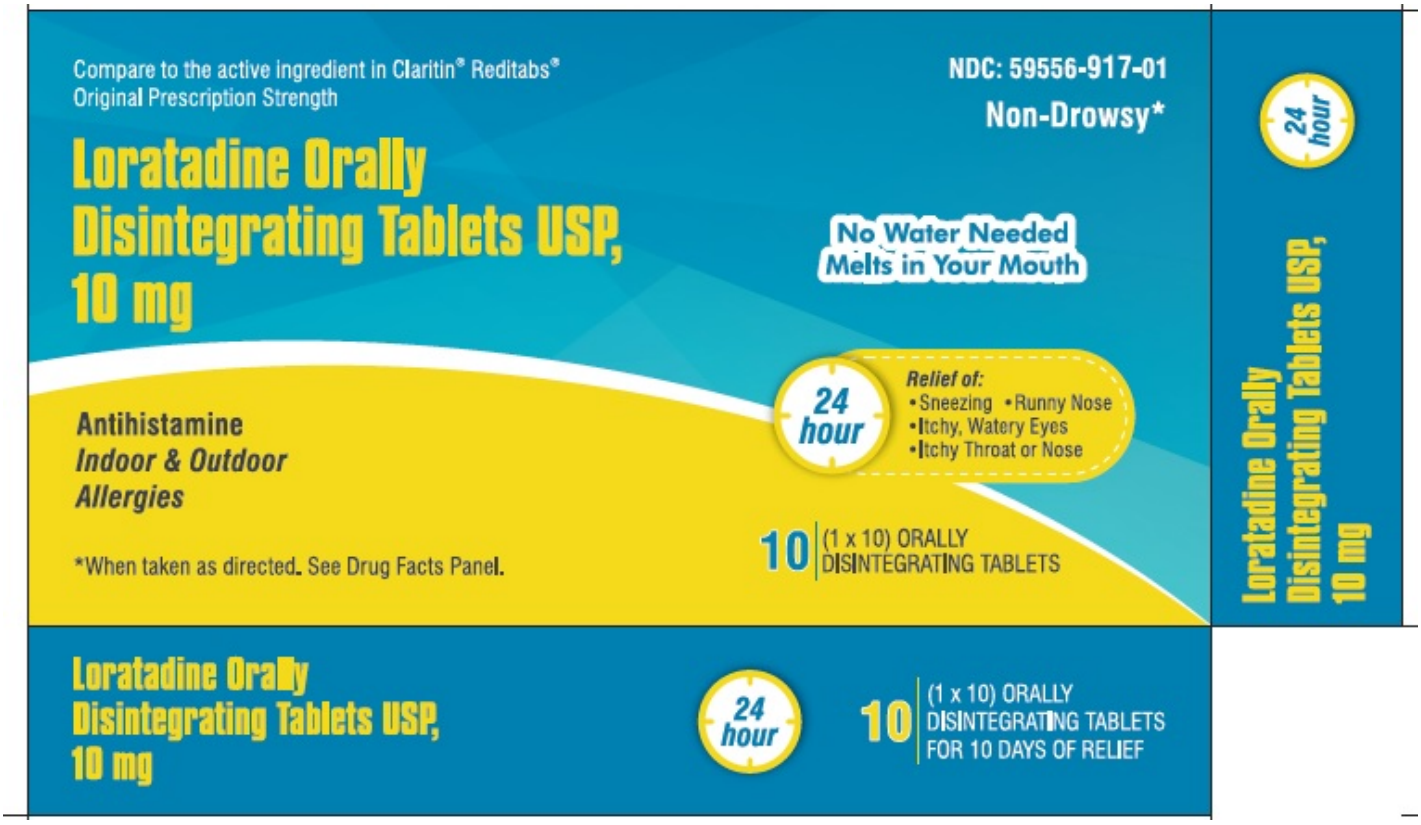
No Water Needed

Melts in Your Mouth

10

ORALLY

DISINTEGRATING TABLETS



LORATADINE

loratadine tablet, orally disintegrating

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59556-917
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN)	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:59556-917-02	2 in 1 CARTON	08/10/2021	
1		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:59556-917-03	3 in 1 CARTON	08/10/2021	
2		30 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:59556-917-05	5 in 1 CARTON	08/10/2021	
3		50 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:59556-917-06	6 in 1 CARTON	08/10/2021	
4		60 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:59556-917-04	4 in 1 CARTON	08/10/2021	
5		40 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:59556-917-01	1 in 1 CARTON	08/10/2021	
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	08/10/2021	

Labeler - Strides Pharma Inc (078868278)

Establishment

Name	Address	ID/FEI	Business Operations
Tenshi Kaizen Pvt Ltd		675478488	analysis(59556-917) , manufacture(59556-917) , pack(59556-917)

Revised: 1/2024

Strides Pharma Inc