

**ALLERVARX- loratadine tablet, orally disintegrating**  
**Innovus Pharmaceuticals, Inc.**

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**Allervarx Loratadine Orally Disintegrating Tablets USP**

***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?**

1-888-278-1784 - 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.

NO VARNISH ZONE

NDC: 57483-950-10

COMPARE TO THE ACTIVE INGREDIENT IN CLARITIN®  
REDITABS® ORIGINAL PRESCRIPTION STRENGTH\*\*

AllerVarx®

# Loratadine Orally Disintegrating Tablets USP, 10 mg

Antihistamine  
Indoor & Outdoor Allergies

**NON-DROWSY\*** **30 (3X10) ORALLY DISINTEGRATING TABLETS**  
**FOR 30 DAYS OF RELIEF**

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

**24 HOURS**

- Relief Of
- Sneezing
  - Runny Nose
  - Itchy, Watery Eyes
  - Itchy Throat or Nose



No Water Needed  
Melts in Your Mouth

AllerVarx®  
Loratadine Orally Disintegrating Tablets USP, 10 mg  
Antihistamine



No Water Needed  
Melts in Your Mouth

**24 HOURS**

**24 HOURS**  
 Loratadine Orally Disintegrating Tablets USP, 10 mg Antihistamine

**Drug Facts**

Active ingredient (in each tablet)	Purpose
Loratadine 10 mg	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 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

**Drug Facts (Continued)**

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

Follow these directions carefully. Do not attempt to push the tablet through the foil.

1. Peel back outer edge.
2. Gently push tablet out.

No water needed  
Melts in your mouth

3. Place the tablet on tongue and close mouth. The tablet will disintegrate.

NO VARNISH ZONE  
Size: 64 x 19 mm

\*\*This product is not manufactured or distributed by Bayer Healthcare LLC, distributor of Claritin® Reditabs®. Bayer Healthcare LLC is the owner of the registered trademark Claritin® Reditabs®.

Distributed By: Inovus Pharmaceuticals, Inc.  
 Englewood, CO 80112  
 www.ayrthealth.com  
 Made in India

Recyclable Carton



Code No.: KR/DRUGS/RT/25/0669/2017  
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## ALLERVARX

loratadine tablet, orally disintegrating

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:57483-950
<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

**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:57483-950-10	3 in 1 CARTON	05/30/2022	
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	ANDA213294	05/30/2022	

**Labeler** - Innovus Pharmaceuticals, Inc. (962507187)**Establishment**

Name	Address	ID/FEI	Business Operations
Tenshi Kaizen Pvt Ltd		675478488	manufacture(57483-950) , pack(57483-950) , analysis(57483-950)

Revised: 12/2024

Innovus Pharmaceuticals, Inc.