

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

-----  
**Allervarx Loratadine Orally Disintegrating Tablets USP, 5 mg**

***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?**

1-888-278-1784 - 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.



## ALLERVARX

loratadine tablet, orally disintegrating

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:57483-955
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

**Ingredient Name**

**Basis of Strength**

**Strength**

<b>LORATADINE</b> (UNII: 7AJ03BO7QN) (LORATADINE - UNII:7AJ03BO7QN)		LORATADINE	5 mg	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>		<b>Strength</b>		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
PULLULAN (UNII: 8ZQ0AYU1TT)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
MANNITOL (UNII: 3OWL53L36A)				
<b>Product Characteristics</b>				
<b>Color</b>	white	<b>Score</b>	no score	
<b>Shape</b>	ROUND	<b>Size</b>	12mm	
<b>Flavor</b>	PEPPERMINT	<b>Imprint Code</b>	T5	
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:57483-955-05	3 in 1 CARTON	08/01/2022	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
ANDA	ANDA212795	06/04/2022		

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

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Tenshi Kaizen Pvt Ltd		675478488	manufacture(57483-955) , pack(57483-955) , analysis(57483-955)

Revised: 6/2022

Innovus Pharmaceuticals, Inc.