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			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:57483-955
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:57483-955-05	3 in 1 CARTON	08/01/2022	
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	ANDA212795	06/04/2022	

Labeler - Innovus Pharmaceuticals, Inc. (962507187)

Establishment

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

Revised: 12/2024 Innovus Pharmaceuticals, Inc.