LORATADINE- loratadine tablet, orally disintegrating
Advagen Pharma Limited

Drug Facts	
Active ingredient (in each tablet)	***Purpose***
Loratadine USP, 10 mg…….....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 a 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 ■ Phenylketonurics: contains phenylalanine (a component of aspartame) 1.52 mg per 10 mg orally disintegrating tablet. ■ safety sealed: do not use if the individual blister unit imprinted with Loratadine Orally Disintegrating Tablets USP 10 mg is open or torn ■ store between 20° to 25°C (68° to 77°F) ■ use tablet immediately after opening individual blister ■ FDA approved acceptance criteria for assay and organic impurities differs from USP test	
Inactive ingredients aspartame, colloidal silicon dioxide, crospovidone,	

magnesium stearate, maize starch, mannitol, microcrystalline cellulose, peppermint flavor, sodium stearyl fumarate
Questions or comments? **Advagen - 888-413-0949**
Distributed by: **Advagen Pharma Ltd** **666 Plainsboro Road** **Suite 605** **Plainsboro, NJ 08536, USA.** **Manufactured by:** **Rubicon Research Private Limited** **Ambernath, Dist: Thane, 421506 India.**

Note: Imprint Code - Λ indicated as UpArrowhead in Drug Listing Data Element (DLDE) section.

PRINCIPAL DISPLAY PANEL

Loratadine Orally Disintegrating Tablets USP 10 mg - 10 Tablets - NDC 72888-029-09

Loratadine Orally Disintegrating Tablets USP 10 mg - 30 Tablets - NDC 72888-029-11

LORATADINE

loratadine tablet, orally disintegrating

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72888-029
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**
ASPARTAME (UNII: Z0H242BBR1)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPOVIDONE (UNII: 2S7830E561)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
MANNITOL (UNII: 3OWL53L36A)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	

Product Characteristics

Color	white (White to Off-White)	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor	PEPPERMINT	**Imprint Code**	UpArrowhead43
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72888-029-09	1 in 1 CARTON	09/10/2020	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:72888-029-11	3 in 1 CARTON	09/10/2020	
2		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	ANDA214280	09/10/2020	

Labeler - Advagen Pharma Limited (051627256)

Registrant - Rubicon Research Private Limited (918629544)

Establishment

Name	Address	ID/FEI	Business Operations
Rubicon Research Private Limited		677604197	manufacture(72888-029) , analysis(72888-029) , pack(72888-029)

Revised: 9/2020 Advagen Pharma Limited