

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	
<ul style="list-style-type: none"> ■ 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	
<ul style="list-style-type: none"> ■ 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

Original Prescription Strength

NDC 72888-029-09

24 Hours

Loratadine

*Non Drowsy

Orally Disintegrating Tablets USP/antihistamine

10 mg

Indoor & Outdoor Allergies

Relief of

- Sneezing
- Runny nose
- Itchy, watery eyes
- Itchy throat or nose

No Water Needed
Melts in your mouth

*When taken as directed. see Drug Facts Panel

10 Orally Disintegrating Tablets

Loratadine

Orally Disintegrating Tablets USP 10 mg

24 Hours

10 orally disintegrating tablets for 10 days of relief

Loratadine
Orally Disintegrating Tablets USP

10 mg
24 Hours

Drug Facts

Active ingredient (in each tablet)
Loratadine USP, 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.

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Drug Facts (Continued)

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

- phenylethanolamine: contains phenylethanolamine (a component of aspartame) 1.52 mg per 10 mg orally disintegrating tablet.
- safety seal: 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, croscopolone, magnesium stearate, maize starch, mannitol, microcrystalline cellulose, peppermint flavor, sodium stearyl fumarate

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

Questions or comments?
Advagen - 888-413-0949



1 Peel back inner edge



2 Gently push tablet out



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

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N 3117288810290912

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

Original Prescription Strength

NDC 72888-029-11

24 Hours

Loratadine^{*Non Drowsy}

Orally Disintegrating Tablets USP/antihistamine

10 mg

Indoor & Outdoor Allergies

Relief of

- Sneezing
- Runny nose
- Itchy, watery eyes
- Itchy throat or nose

No Water Needed
Melts in your mouth

*When taken as directed. see Drug Facts Panel

30 Orally Disintegrating Tablets

Loratadine

Orally Disintegrating Tablets USP 10 mg

24 Hours

30 orally
disintegrating tablets
for 30 days of reliefOrally Disintegrating Tablets USP
Loratadine

10 mg

24 Hours

Drug Facts**Active ingredient (in each tablet)**

Loratadine USP, 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.

Drug Facts (Continued)**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

- **pharmaceuticals:** contains phenylephrine (a component of aspartame) 1.52 mg per 10 mg orally disintegrating tablet.
- **safety seal:** 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, croscopolone, magnesium stearate, maize starch, mannitol, microcrystalline cellulose, peppermint flavor, sodium stearyl fumarate

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**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: 7AJ03BO7QN) (LORATADINE - UNII:7AJ03BO7QN)	LORATADINE	10 mg

Inactive Ingredients

Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPROVIDONE (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	10 mm
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