

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 - 866-488-0312

Distributed by:

Advagen Pharma Ltd

East Windsor, NJ 08520, USA

Manufactured by:

Rubicon Research Ltd.,

Thane 421506, India.

Rev. 02, 11/24

Note: Imprint Code - A 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

^{*Non Drowsy}
Loratadine
Orally Disintegrating Tablets USP/antihistamine

10 mg

Indoor & Outdoor Allergies

24 Hours

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

^{*Non Drowsy}
Loratadine
Orally Disintegrating Tablets USP

10 mg

24 Hours

Relief of :

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

10 orally disintegrating tablets

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

- phenylethanolamine: contains phenylethanolamine (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, croscopolidone, 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.

Directions or comments?
Advagen - 866-488-0312

 1. Peel back inner edge

 2. Gently push tablet out

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

Mfg. Lic. No. KD-682
Distributed by : **Advagen Pharma Ltd.**,
East Windsor, NJ 08520, USA
Manufactured by: **Rubicon Research Ltd.**, Thane 421506, India.
Rev.02, 11/24

Package insert available at
<https://www.advagenpharma.com/pil/loratadineorallydisintegratingtablets>



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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: 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 | 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 Limited (918629544)

Establishment

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