

LORATADINE ODT - loratadine tablet, orally disintegrating
Better Living Brands, LLC

Loratadine Orally Disintegrating Tablets USP 10 mg

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
- sneezing
- itchy, watery eyes
- 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 (1-800-222-1222) 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 2.25 mg per tablet
- do not use if the individual blister unit is open or torn
- store at 20° to 25°C (68° to 77°F)
- use tablet immediately after opening individual blister
- Complies with USP test 2 for Disintegration

Inactive ingredients

aspartame, crospovidone, mannitol, microcrystalline cellulose, peppermint, pregelatinized starch (maize), sodium stearyl fumarate

Questions or comments?

call **1-855-274-4122**

DISTRIBUTED BY:

BETTER LIVING BRANDS LLC
P.O.BOX 99
PLEASANTON, CA 94566-0009
†1-888-723-3929

Made in India

Code: TS/DRUGS/22/2009

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 10 mg, Blister Carton 30 (3 X 10) Orally Disintegrating Tablets

Signature

care[®]

Quality Guaranteed

**Compare to the
Claritin[®] RediTabs[®]
active ingredient****

NDC 21130-221-84

NON-DROWSY*

Allergy Relief

LORATADINE ORALLY DISINTEGRATING TABLETS USP 10 mg

Antihistamine

No Water Needed, Melts in Your Mouth

Original Prescription Strength

Indoor & Outdoor Allergies

24 Hour Relief of:

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

***When taken as directed. See Drug Facts Panel.**

Actual Size

**30 ORALLY DISINTEGRATING
TABLETS**

1/2

GLUE - NO COATING

This product is not manufactured or distributed by Bayer Healthcare LLC, distributor of Claritin® RediTabs®.

Questions or comments? Call 1-855-274-4422

Inactive Ingredients

- aspartame, croscellose, mannitol, microcrystalline cellulose, pepsin, pregelatinized starch (maize), sodium stearoyl fumarate
- Other information
- Phenylephrine: contains phenylephrine 22.5 mg per tablet
- do not use if the individual blister unit is open or torn
- store at 20° to 25°C (68° to 77°F)
- use tablet immediately after opening individual blister
- complies with USP B_{12} for disintegration

ask a doctor	consumers with liver or kidney disease
ask a doctor	6 years of age
ask a doctor	children under 6 years and over
1 tablet daily, not more than 1 tablet in 24 hours	adults and children

Directions: place 1 tablet on tongue; tablet disintegrates, without water

Drug Facts (continued)

Drug Facts

Active ingredient (in each tablet): Loratadine USP 10 mg, antihistamine

Purpose

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: runny nose, sneezing, itchy, watery eyes, 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 as directed. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

If pregnant or breast-feeding, ask a health professional before use.



Allergy Relief
LORATADINE ORALLY DISINTEGRATING TABLETS
USP 10 mg
Antihistamine



Compare to the Claritin® RediTabs® active ingredient**
NDC 21130-221-84

NON-DROWSY*
Allergy Relief
LORATADINE ORALLY DISINTEGRATING TABLETS USP 10 mg
Antihistamine

No Water Needed, Melts in Your Mouth

30 ORALLY DISINTEGRATING TABLETS



Lot: P1052466
EXP: LM-5349
Unvarnished Zone

Instructions for Opening Blister Pack

- Do not push the tablet from the back
- Bend and tear blister at perforation
- Peel off the top. Gently push tablet out.
- Place the tablet on tongue and close mouth. The tablet will disintegrate.

DISTRIBUTED BY: BETTER LIVING BRANDS LLC, P.O. BOX 99, PLEASANTON, CA 94566-0099, 1-888-723-3929, Made in India Code: TS/DRUGS/22/2009

LORATADINE ODT
loratadine tablet, orally disintegrating

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-221
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)	
CROSPROVIDONE (120 .MU.M) (UNII: 68401960MK)	
MANNITOL (UNII: 3OWL53L36A)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
PEPPERMINT (UNII: V95R5KMY2B)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	

Product Characteristics

Color	WHITE (White to Off-white)	Score	no score
Shape	ROUND (Biconvex)	Size	8mm
Flavor	PEPPERMINT	Imprint Code	K;9
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-221-84	3 in 1 CARTON	09/20/2023	
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	ANDA208477	09/20/2023	

Labeler - Better Living Brands, LLC (009137209)**Registrant** - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(21130-221) , MANUFACTURE(21130-221)

Revised: 9/2023

Better Living Brands, LLC