

LORATADINE ODT - loratadine tablet, orally disintegrating
Ahold U.S.A., Inc,

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
FOODHOLD U.S.A., LLC
LANDOVER, MD 20785
1-877-846-9949
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Made in India
Quality guaranteed
or your money back.
Code: TS/DRUGS/22/2009

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 10 mg, Blister Carton 10 (1 X 10) Orally Disintegrating Tablets

CAREONE®

NDC 60000-950-83

**Compare to the active ingredient
in Claritin® RediTabs®†
24 hr**

**Original Prescription Strength
Non-Drowsy***

Allergy Relief

Loratadine Orally Disintegrating
Tablets USP 100 mg

No water needed,
melts in your mouth

Actual Size

10 Orally Disintegrating Tablets

Indoor & Outdoor Allergies

Relief of:

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

No Water Needed

Melts in Your Mouth

*When taken as directed.

See Drug Facts Panel.

GLUE - NO COATING

Drug Facts

Active ingredient (in each tablet)
Loratadine USP 10 mg.....Antihistamine

Purpose
Loratadine USP 10 mg.....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. →

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 tartrate: Contains phenylethanolamine 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, croscopolone, mannitol, microcrystalline cellulose, peppermint, pregelatinized starch (maize), sodium stearyl fumarate

Questions or comments? call 1-855-274-4122



LM-2784

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

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CAREONE[®]
NDC 60000-950-83

Compare to the active ingredient in Claritin® RediTabs*†

24hr

Original Prescription Strength
Non-Drowsy*

Allergy Relief

Loratadine Orally Disintegrating Tablets USP 10 mg

Antihistamine

No water needed, melts in your mouth

Actual Size **10**

Orally Disintegrating Tablets

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.

OUR PHARMACISTS RECOMMEND

Instructions for Opening Blister Pack

1. Bend and tear blister at perforation
2. Peel off the blister pack
3. Place the tablet on tongue

LORATADINE ODT			
loratadine tablet, orally disintegrating			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60000-950
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)	
CROSPVIDONE (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:60000-950-83	1 in 1 CARTON	04/11/2018	
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	04/11/2018	

Labeler - Ahold U.S.A., Inc, (188910863)**Registrant** - Aurohealth LLC (078728447)**Establishment**

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(60000-950) , MANUFACTURE(60000-950)

