

**LORATADINE ODT - loratadine tablet, orally disintegrating  
DISCOUNT DRUG MART**

-----  
**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:** Discount Drug Mart  
211 Commerce Drive, Medina, OH 44256  
www.discount-drugmart.com

Made in India  
Code: TS/DRUGS/22/2009

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

**NDC 53943-035-03**

\*\*Compare to the active ingredient  
in Claritin® RediTabs®

**DISCOUNT  
drug mart**

***Original Prescription Strength***

**Indoor & Outdoor Allergies**

**No Water Needed  
Melts in Your Mouth**

***Non-Drowsy\****

**Lortadine**

**Orally Disintegrating Tablets USP 10 mg**

**24 Hour Relief of:**

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

***Antihistamine***

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

**10 (1 X 10) Orally Disintegrating Tablets**

**Drug Facts**

**Active ingredient (in each tablet)**  
Loratadine USP 10 mg

**Purpose**  
Antihistamine

**Uses**  
Temporary relief of these symptoms due to hay fever or other upper respiratory allergies: ■ 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: 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  
■ Completes with USP test 2 for Disintegration

**Inactive ingredients**  
aspartame, croscopolldone, mannitol, microcrystalline cellulose, peppermint, pregelatinized starch (maize), sodium stearyl fumarate

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

---

Lot: \_\_\_\_\_  
Exp.: \_\_\_\_\_

**Distributed by:** Discount Drug Mart  
211 Commerce Drive, Medina, OH 44256  
www.discount-drugmart.com

Made in India Code: TS/DRUGS/22/2009

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



---

**Original Prescription Strength**



**Indoor & Outdoor Allergies**

**Non-Drowsy\*  
Loratadine**

**Orally Disintegrating Tablets USP 10 mg**

**Antihistamine**

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

NDC 53943-035-03

\*\*Compare to the active ingredient in Claritin® RediTabs\*

**No Water Needed  
Melts in Your Mouth**

**24 Hour Relief of:**

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

**10 (1 X 10) Orally Disintegrating Tablets**

**SATISFACTION GUARANTEED**  
IF DISSATISFIED, RETURN UNUSED PORTION AND PACKAGE TO STORE WHERE PURCHASED. IF UNABLE TO RETURN TO STORE, SEND REASON FOR DISSATISFACTION, NAME, ADDRESS AND EMPTY PACKAGE TO: DISCOUNT DRUG MART, 211 COMMERCE DRIVE, MEDINA, OHIO 44256

---

**Instructions for Opening Blister Pack**

Do not push the tablet from the back



1. Band and tear blister at perforation



2. Peel off the foil. Gently push tablet out.



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



Unvarnished Zone  
(dotted line not for printing)

## LORATADINE ODT

loratadine tablet, orally disintegrating

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53943-035
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LORATADINE (UNII: 7AJ03B07QN) (LORATADINE - UNII: 7AJ03B07QN)	LORATADINE	10 mg

## Inactive Ingredients

Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	
CROSPVIDONE (15 MPA.S AT 5%) (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:53943-035-03	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** - DISCOUNT DRUG MART (047741335)

**Registrant** - Aurohealth LLC (078728447)

## Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(53943-035) , MANUFACTURE(53943-035)