

**LORATADINE OD- loratadine tablet, orally disintegrating  
Fred's Inc.**

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**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 (1-800-222-1222).

**DIRECTIONS**

- place 1 tablet on tongue; tablet disintegrates, with or without water

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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

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## **OTHER INFORMATION**

- Phenylketonurics: Contains Phenylalanine 0.6 mg Per Tablet.
- **TAMPER EVIDENT: DO NOT USE IF BLISTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING.**
- store between 20° to 25° C (68° to 77° F). Protect from excessive moisture.
- keep in a dry place.
- use tablet immediately after opening individual blister.

## **INACTIVE INGREDIENTS**

Aspartame, croscarmellose sodium, fruit flavors, magnesium stearate, mannitol, sodium stearyl fumarate

## **QUESTIONS?**

Call 1-800-406-7984

## **PRINCIPAL DISPLAY PANEL**

**fred's**

**Non-Drowsy\***

**Allergy Relief**

**Loratadine Orally Disintegrating Tablets, 10 mg**

**Antihistamine**

**No Water Needed, Melts In Your Mouth!**

**INDOOR & OUTDOOR ALLERGIES**

**24 hour relief of:**

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

**Compare To Active Ingredient of Claritin® RediTabs®†**

**30 Orally Disintegrating Tablets**

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

**DISTRIBUTED BY: fred's, Inc.**

**5091232/R1111**

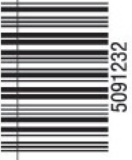
**Drug Facts**  
**Active ingredient (in each tablet)**  
 Loratadine, USP 10 mg.....Antihistamine  
**Purpose**

**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 (1-800-222-1222).

**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 0.6 mg Per Tablet.  
 ■ TAMPER EVIDENT: DO NOT USE IF BLISTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING.



**fred's** Non-Drowsy\*  
**Allergy Relief**  
 Loratadine Orally Disintegrating Tablets, 10 mg

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 Allergy Relief  
 Loratadine Orally Disintegrating Tablets, 10 mg  
 Antihistamine

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 INDOOR & OUTDOOR ALLERGIES

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

**30 Orally Disintegrating Tablets**

Shown at Actual Size

Compare To  
 Active ingredient of  
 Claritin® RediTabs®

LAB TESTED  
 Lab Tested for Quality  
 Used Tested for Satisfaction

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



Expiration Date:  
 Batch No.

Keep the carton.  
 It contains important  
 information. See end  
 panel for expiration date.

Non Varnish Area

**Drug Facts (continued)**  
 ■ store between 20° to 25° C (68° to 77° F). Protect from excessive moisture.  
 ■ keep in a dry place.  
 ■ use tablet immediately after opening individual blister.  
**Inactive ingredients** aspartame, croscarmellose sodium, fruit flavors, magnesium stearate, mannitol, sodium stearyl fumarate

**Questions?** call 1-800-406-7984

The product is not manufactured or distributed by Schering-Plough Healthcare Products, Inc. CLARITIN® and REDITABS® are registered trademarks of Schering Corporation.

DISTRIBUTED BY: fred's, Inc.  
 4300 NEW GETWELL RD, MEMPHIS, TN 38118  
 www.fredsinc.com

**fred's Promise**  
 Not Happy With This Product?  
 Just Bring It Back For a Refund!

R1111

# LORATADINE OD

loratadine tablet, orally disintegrating

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55315-529
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN)	LORATADINE	10 mg

## Inactive Ingredients

Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	

## Product Characteristics

<b>Color</b>	white (White to Off-White)	<b>Score</b>	no score
<b>Shape</b>	ROUND (Flat Faced Beveled Edge)	<b>Size</b>	10mm
<b>Flavor</b>	FRUIT	<b>Imprint Code</b>	RC17
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55315-529-31	30 in 1 BLISTER PACK		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077153	08/31/2007	

**Labeler** - Fred's Inc. (005866116)

**Registrant** - Ranbaxy Pharmaceuticals Inc. (937890044)

## Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		051565745	manufacture(55315-529)

Revised: 1/2013

Fred's Inc.