## LORATADINE ODT- loratadine tablet, orally disintegrating Safeway 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

laduits 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 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 OR COMMENTS?**

Call 1-888-SAFEWAY

#### PRINCIPAL DISPLAY PANEL

NDC 21130-527-69

Compare to Claritin® RediTabs® active ingredient†

**Original Prescription Strength** 

Non-Drowsv\*

24-Hour Allergy Relief

Loratadine Orally Disintegrating Tablets, 10 mg

**Antihis tamine** 

#### **Indoor & Outdoor Allergies**

- No Water Needed
- Melts in Your Mouth

#### Relief of:

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

For Adults and Children Six Years and Older

See Drug Facts Panel.

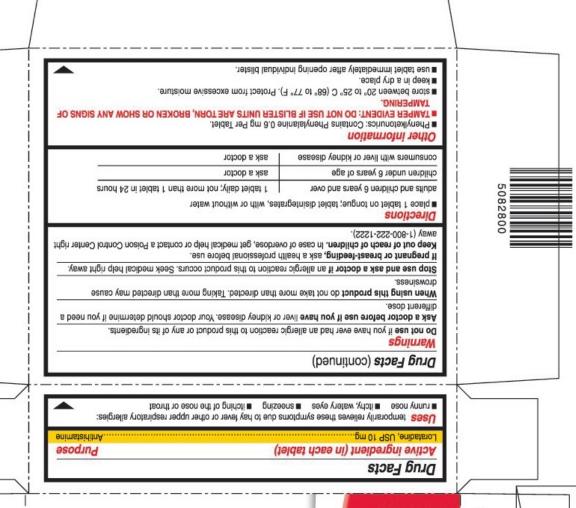
10 ORALLY DISINTEGRATING TABLETS

**SAFEWAY**<sub>TM</sub>

DISTRIBUTED BY SAFEWAY INC.

5082800/R0212

<sup>\*</sup>When taken as directed.



NDC 21130-527-69 Compare to Claritin® RediTabs® active ingredient

Original Prescription Strength

Non-Drowsy\*

# 24-Hour Allergy Relief

Loratadine Orally Disintegrating Tablets, 10 mg **Antihistamine** 

**Indoor & Outdoor Allergies** 

No Water Needed • Melts in Your Mouth

Relief of: • Sneezing • Runny Nose • Itchy, Watery Eyes Itchy Throat or Nose

For Adults and Children Six Years and Older



### 10 ORALLY DISINTEGRATING TABLETS

SAFEWAY ()

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

Guestions or comments? Call 1-888-SAFEWAY

sodium stearyl fumarate

Inactive ingredients aspartame, croscarmellose sodium, fruit flavors, magnesium stearate, mannitol,

Drug Facts (continued)

Non Varnish Area

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

## LORATADINE ODT

loratadine tablet, orally disintegrating

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-527
Route of Administration	ORAL		

l	Active Ingredient/Active Moiety			
l	Ingredient Name	Basis of Strength	Strength	
l	LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN)	LORATADINE	10 mg	

Inactive Ingredients				
Ingredient Name	Strength			
ASPARTAME (UNII: Z0H242BBR1)				
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MANNITOL (UNII: 3OWL53L36A)				
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)				

Product Characteristics				
Color	white (White to Off-White)	Score	no score	
Shape	ROUND (flat faced beveled edge)	Size	10 mm	
Flavor	FRUIT	Imprint Code	RC17	
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-527-69	10 in 1 BLISTER PACK		
2	NDC:21130-527-31	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 -** Safeway Inc. (009137209)

Establishment				
Name	Address	ID/FEI	Business Operations	
Ohm Laboratories Inc.		051565745	manufacture(21130-527)	

Revised: 9/2012 Safeway Inc.