

LORATADINE ODT- loratadine tablet, orally disintegrating
Safeway Inc.

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

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 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-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

***When taken as directed.**

See Drug Facts Panel.

10 ORALLY DISINTEGRATING TABLETS

SAFEWAY™

DISTRIBUTED BY SAFEWAY INC.

5082800/R0212



Drug Facts (continued)

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.
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.

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.

Original Prescription Strength

Compare to Claritin® RediTabs® active ingredient†

**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

*When taken as directed. See Drug Facts Panel.

10 ORALLY DISINTEGRATING TABLETS

SAFEWAY™

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

Batch No. _____
Expiration Date: _____

Non Varnish Area

Drug Facts (continued)

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

(Questions or comments?) call 1-888-SAFEWAY

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

RD212
DISTRIBUTED BY
SAFEWAY INC.
P.O. BOX 99
PLEASANTON, CA
94568-0099
1-888-SAFEWAY
www.safeway.com



LORATADINE ODT

loratadine tablet, orally disintegrating

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-527
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)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4U)	

Product Characteristics

Color	white (White to Off-White)	Score	no score
Shape	ROUND (flat faced beveled edge)	Size	10mm
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)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment

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

Revised: 9/2012

Safeway Inc.