

**SUNMARK LORATADINE ODT- loratadine tablet, orally disintegrating**  
**Sunmark**

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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

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?**

call **1-800-406-7984**

**Keep the carton. It contains important information.**

**See end panel for expiration date.**

Distributed by McKesson

One Post Street, San Francisco, CA 94104

[www.sunmarkbrand.com](http://www.sunmarkbrand.com)

## **PRINCIPAL DISPLAY PANEL**

**sunmark<sup>®</sup>**

**NDC 49348-930-01**

**allergy relief**

**24 HOUR**

**loratadine Orally Disintegrating Tablets, 10 mg**

**Antihistamine**

**For adults and children six years and older**

**Indoor & Outdoor Allergies**

**Non-drowsy\***

**Relief of sneezing; runny nose; itchy, watery eyes; itchy throat or nose**

**MELTS IN YOUR MOUTH**

**10 ORALLY DISINTEGRATING TABLETS**

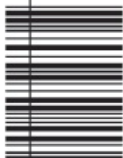
**\*When taken as directed.**

**See Drug Facts Panel.**

**COMPARE TO CLARITIN<sup>®</sup> REDITABS<sup>®</sup> ACTIVE INGREDIENT<sup>†</sup>**

**<sup>†</sup>The product is not manufactured or distributed by Schering-Plough Healthcare Products, Inc.**

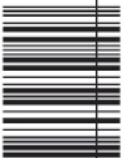
**CLARITIN<sup>®</sup> and REDITABS<sup>®</sup> are registered trademarks of Schering Corporation.**



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**Other information**

■ Phenylephrine: Contains Phenylephrine 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.



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**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

**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



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Empowering Healthcare

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**COMPARE TO CLARITIN® REDITABS®**  
**ACTIVE INGREDIENT†**  
 NDC 49348-930-01

**24 HOUR**

**sunmark®**

**allergy relief**

**loratadine**

**Orally Disintegrating Tablets, 10 mg**

**Antihistamine**

**For adults and children six years and older**

**Indoor & Outdoor Allergies**

**Non-drowsy\***

Relief of sneezing; runny nose;  
 itchy, watery eyes; itchy throat or nose

**MELTS IN YOUR MOUTH**

**10 ORALLY DISINTEGRATING TABLETS**

Actual Size

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

**Drug Facts (continued)**

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

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

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

**Non Varnish Area**

† This product is not manufactured or distributed by Schering-Plough HealthCare Products, Inc., owner of the registered trademarks Claritin® and RedTabs®.  
 Expiration Date: \_\_\_\_\_  
 Batch No. \_\_\_\_\_



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**ACTIVE INGREDIENT†**  
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**24 HOUR**

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**MELTS IN YOUR MOUTH**

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Actual Size

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

**Drug Facts (continued)**

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

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 Expiration Date: \_\_\_\_\_  
 Batch No. \_\_\_\_\_

**sunmark<sup>®</sup>**

**NDC 49348-929-04**

**allergy relief**

**24 HOUR**

**Loratadine Orally Disintegrating Tablets, 10 mg**

**Antihistamine**

**For adults and children six years and older**

**Indoor & Outdoor Allergies**

**Non-drowsy\***

**Relief of sneezing; runny nose; itchy, watery eyes; itching of nose & throat**

**MELTS IN YOUR MOUTH**

**24 ORALLY DISINTEGRATING TABLETS**

**\*When taken as directed.**

**See Drug Facts Panel.**

**COMPARE TO ALAVERT<sup>®</sup> ACTIVE INGREDIENT<sup>†</sup>**

**<sup>†</sup>The product is not manufactured or distributed by Wyeth Consumer Healthcare, owner of the registered trademark Alavert<sup>®</sup>.**



**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**  
 Phenylethanolamines: Contains Phenylethanamine 0.6 mg Per Tablet.  
 TAMPERS 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.  
 Use tablet immediately after opening individual blister.

**Drug Facts**

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

**Purpose**

**sunmark®**

COMPARE TO ALAVERT®  
 ACTIVE INGREDIENT†  
 NDC 49348-929-04

**24 HOUR**

**allergy relief**

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

For adults and children six years and older

**Non-drowsy\***

Indoor & Outdoor Allergies  
 Relief of sneezing; runny nose;  
 itchy, watery eyes; itching of nose & throat

**MELTS IN YOUR MOUTH**

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**Drug Facts (continued)**

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

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

†This product is not manufactured or distributed by Wyeth Consumer Healthcare, owner of the registered trademark Alavert®.

Batch No. \_\_\_\_\_

Expiration Date: \_\_\_\_\_

**Non Varnish Area**

**SUNMARK LORATADINE ODT**  
 loratadine tablet, orally disintegrating

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49348-930
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
LORATADINE (UNII: 7AJ03BO7QN) (LORATADINE - UNII:7AJ03BO7QN)	LORATADINE	10 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
ASPARTAME (UNII: Z0H242BBR1)	
CROSCARMELOSE 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>	STRAWBERRY, TUTTI FRUTTI, MINT	<b>Imprint Code</b>	RC17
<b>Contains</b>			

**Packaging**

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:49348-930-01	10 in 1 BLISTER PACK		
2	NDC:49348-930-44	30 in 1 BLISTER PACK		

**Marketing Information**

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

**SUNMARK LORATADINE ODT**

loratadine tablet, orally disintegrating

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49348-929
<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)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4U)	

**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>	STRAWBERRY, TUTTI FRUTTI, MINT	<b>Imprint Code</b>	RC17
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49348-929-04	24 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** - Sunmark (177667227)**Registrant** - Ranbaxy Pharmaceuticals Inc. (937890044)**Establishment**

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		051565745	manufacture(49348-930, 49348-929)

Revised: 8/2012

Sunmark