LORATADINE- loratadine tablet, orally disintegrating American Sales Company

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

1 tablet daily; not more than 1 tablet in 24 hours
ask a doctor
e 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

PRINCIPAL DISPLAY PANEL

Compare to the active ingredient of Claritin ${}^{\mathbb{R}}\mathbf{Reditabs}^{\,\mathbb{R}^{\,\dagger}}$

CAREONE®

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

FOR ADULTS AND CHILDREN SIX YEARS AND OLDER!

Relief of:

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

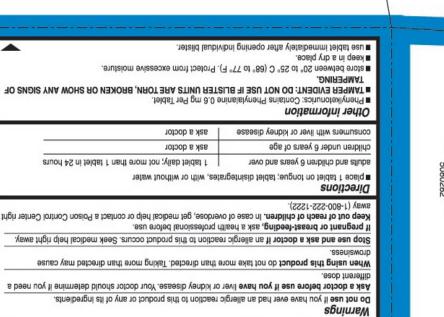
10 Orally Disintegrating Tablets

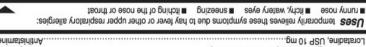
See Drug Facts Panel.

DISTRIBUTED BY: AMERICAN SALES COMPANY

5080282/R0211

^{*}When taken as directed.





Active ingredient (in each tablet)

Drug Facts

Non Varnish Area

Drug Facts (continued)

Antihistamine Purpose

Compare to the active ingredient of

RediTabs®1

Actual Size

CAREONE® Original Prescription Strength

Non-Drowsy'

Loratadine Orally Tablets, 10 mg / Antihistamine

Indoor & Outdoor Allergies

- · Itchy, Watery Eyes
- Itchy Throat or Nose

Relief of: · Sneezing · Runny Nose

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

sodium stearyl fumarate

Tablets

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

Drug Facts (continued)

Questions? call 1-800-406-7984

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AMERICAN SALES COM
4201 WALDEN AVENUE

LANCASTER, NY 14086 www.care1.info ©2011 S&S Brands, Inc.

Compare to the active ingredient of Claritin®RediTabs®†

CAREONE®

Original Prescription Strength

CHILDREN'S Non-Drowsy*

24 hour

ALLERGY RELIEF

Loratadine Orally Disintegrating Tablets, 10 mg/Antihistamine

Indoor & Outdoor Allergies

NO WATER NEEDED • MELTS IN YOUR MOUTH

FOR ADULTS AND CHILDREN SIX YEARS AND OLDER!

Relief of:

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
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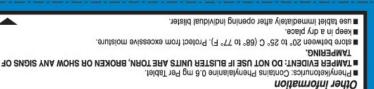
10 Orally Disintegrating Tablets

See Drug Facts Panel.

DISTRIBUTED BY: AMERICAN SALES COMPANY

5080281/R0211

^{*}When taken as directed.



consumers with liver or kidney disease язк я достог children under 6 years of age ask a doctor

> ■ place 1 tablet on tongue; tablet disintegrates, with or without water Directions

> > away (1-800-222-1222).

adults and children 6 years and over

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right If pregnant or breast-feeding, ask a health professional before use.

1 tablet daily; not more than 1 tablet in 24 hours

Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away. drowsiness.

When using this product do not take more than directed. Taking more than directed may cause

Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a Do not use if you have ever had an allergic reaction to this product or any of its ingredients. Warnings

Drug Facts (continued)

■ runny nose ■ itchy, watery eyes ■ sneezing ■ itching of the nose or throat USes temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: Antihistamine Loratadine, USP 10 mg.... Active ingredient (in each tablet) əsodınd

Drug Facts

Tablets, 10 mg/Antihistamine

Indoor & Outdoor Allergies

NO WATER NEEDED - MELTS IN YOUR MOUTH FOR ADULTS AND CHILDREN SIX YEARS AND OLDER!

> · Sneezing · Runny Nose · Itchy, Watery Eyes

Itchy Throat or Nose

Relief of:

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

Questions? call 1-800-406-7984

sodium stearyl fumarate

Orally Disintegrating Tablets

Non Varnish Area

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

Drug Facts (continued)

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LANCASTER, NY 14086
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ality guaranteed or your money



Actual Size



LORATADINE

loratadine tablet, orally disintegrating

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41520-525

Route of Administration 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: M28 OL1HH48)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MANNITOL (LINII: 20WI 531 36 A)		

MANNITOL (UNII: 30WL53L36A)

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

ш				
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:41520-525-69	10 in 1 BLISTER PACK		

Marketing Information

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

LORATADINE

loratadine tablet, orally disintegrating

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:41520-527

ORAL

Active Ingredient/Active Moiety

I	Ingredient Name	Basis of Strength	Strength
I	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)

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Labeler - American Sales Company (809183973)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment					
Name	Address	ID/FEI	Business Operations		
Ohm Laboratories Inc.		184769029	manufacture(41520-525, 41520-527)		

Revised: 1/2013 American Sales Company