LORATADINE- loratadine tablet, orally disintegrating Select Brand

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

| ladilite and enlidren 6 Vears 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

PRINCIPAL DISPLAY PANEL

select brand®

NDC 15127-979-10

NON-DROWSY*

Original Prescription Strength

Allergy Relief Tablets

Loratadine Orally Disintegrating Tablets, 10 mg

Antihis tamine

24 Hour Allergy Relief

Indoor & Outdoor Allergies

No Water Needed

Melts in Your Mouth

Relief of: Sneezing; Runny Nose;

Itchy, Watery Eyes; Itchy Throat or Nose

For Adults & Children six years & older!

10 Orally Disintegrating Tablets

■ Compare to the active ingredient of Claritin® RediTabs®

Distributed by: SELECT BRAND® DISTRIBUTORS

5079375/R0610

^{*}When taken as directed. See Drug Facts Panel.



Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:15127-979

Route of Administration ORAL

Active Ingredient/Active Moiety

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

Inactive Ingredients Ingredient Name Strength ASPARTAME (UNII: Z0H242BBR1) CROSCARMELLOSE SODIUM (UNII: M28 OL 1HH48) MAGNESIUM STEARATE (UNII: 70097M6 I30) MANNITOL (UNII: 3OWL53L36 A) 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:15127-979-10 | 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 | | |
| | | | | |

Labeler - Select Brand (043562370)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

| Establishment | | | |
|-----------------------|---------|-----------|------------------------|
| Name | Address | ID/FEI | Business Operations |
| Ohm Laboratories Inc. | | 051565745 | manufacture(15127-979) |

Revised: 10/2012 Select Brand