**GUARDIAN LORATADINE - loratadine tablet**
**Guardian Drug Company**

---

**Guardian Loratadine Tablets**

**ACTIVE INGREDIENT (in each tablet)**

Loratadine USP, 10mg

**PURPOSE**

Antihistamine

**USE(S)**

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itchy, watery eyes
- 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 DOCTOR IF**

an allergic reaction to this product occurs. Seek medical help right away.

**IF PREGNANT OR BREASTFEEDING,**

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.

**DIRECTIONS**

| | |
|---|---|
| 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**

- Store at 20º to 25ºC (68º to 77ºF) [See USP Controlled Room Temperature]
- Protect from excessive moisture

SAFETY SEALED: DO NOT USE IF THE IMPRINTED BOTTLE SEAL WITH "SEALED FOR YOUR PROTECTION" IS OPEN OR TORN

**INACTIVE INGREDIENTS**

colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate

**QUESTIONS OR COMMENTS?**

call 1-609-860-2600 Hours: 8am-4pm, EST.

**PRINCIPAL DISPLAY PANEL**

**Guardian**
NDC 53041-285-21

Non-Drowsy*

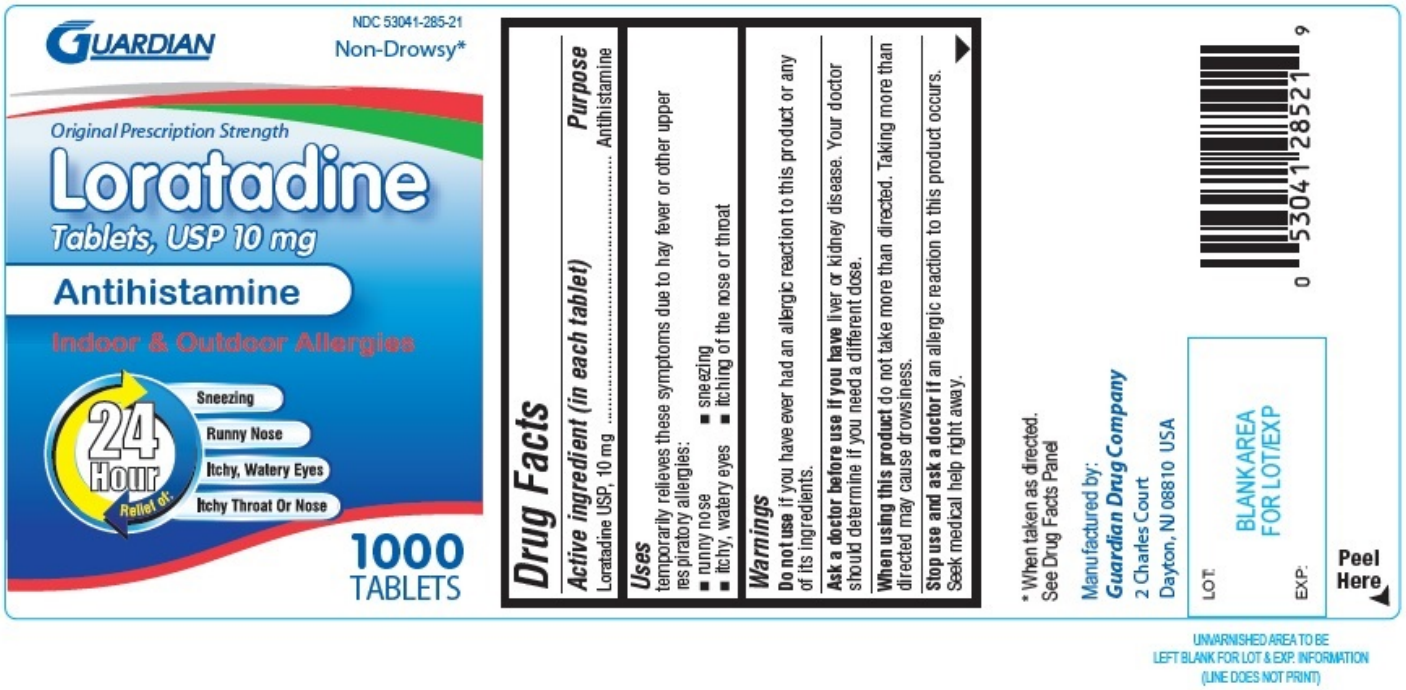
Original Prescription Strength

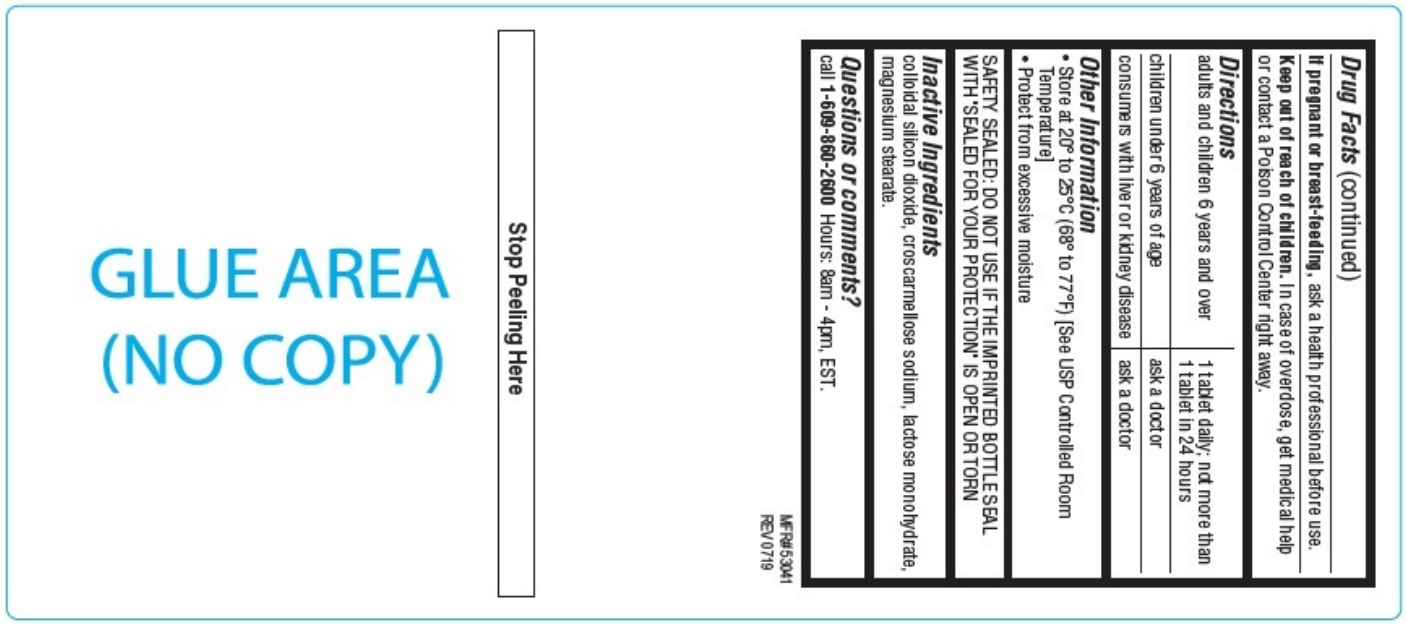
Loratadine
Tablets, USP 10 mg

Antihistamine

Indoor & Outdoor Allergies

24 Hour Relief of:
Sneezing
Runny Nose
Itchy, Watery Eyes
Itchy Throat Or Nose




# GUARDIAN LORATADINE

loratadine tablet

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:53041-285 |
| **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** |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **LACTOSE MONOHYDRATE** (UNII: EWQ57Q8I5X) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | WHITE | **Score** | no score |
| **Shape** | ROUND | **Size** | 6mm |
| **Flavor** | | **Imprint Code** | L |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:53041-285-21 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 07/22/2019 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA207569 | 07/22/2019 | |

## Labeler - Guardian Drug Company (119210276)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Guardian Drug Company | | 119210276 | MANUFACTURE(53041-285) |

Revised: 7/2019 Guardian Drug Company