**LORATADINE- loratadine tablet**
**Apotex Corp.**

---

**Loratadine Tablet 10 mg**

***Drug Facts***

***Active ingredient (in each tablet)***

Loratadine 10 mg

***Purpose***

Antihistamine

***Uses***

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 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.

***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***

- safety sealed: do not use if induction seal, with "Lift N Peel" tab, under cap is broken or missing

- store between 2°C and 30°C (36°F and 86°F)
- protect from excessive moisture

***Inactive ingredients***

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

***Questions or comments?***

Call **1-800-706-5575**, weekdays, 8:30 am - 5:00 pm Eastern Standard Time

| Manufactured by: | Manufactured for: |
|---|---|
| Apotex Inc. | Apotex Corp. |
| Toronto, Ontario | Weston, Florida |
| Canada M9L 1T9 | 33326 |

Revised: August 2018

**PRINCIPAL DISPLAY PANEL - 10 mg**

**APOTEX CORP.** NDC 60505-0147-1

**Loratadine Tablets 10 mg**

***Non-Drowsy****

*Antihistamine/*Original Prescription Strength

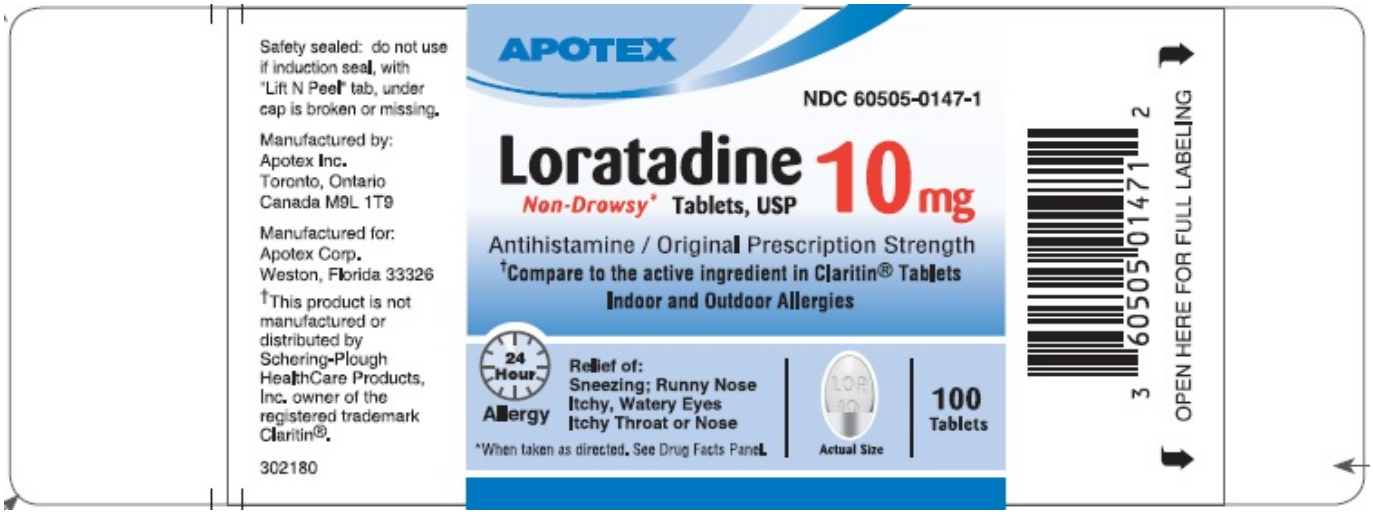
**†Compare to the active ingredient in Claritin® Tablets**

**Indoor & Outdoor Allergies**

**24 hour**

**Relief of**

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



# LORATADINE

loratadine tablet

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:60505-0147 |
| **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) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | WHITE | **Score** | no score |
| **Shape** | OVAL | **Size** | 8mm |
| **Flavor** | | **Imprint Code** | LOR;10;APO |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:60505-0147-1 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 01/24/2005 | 06/30/2022 |
| **2** | NDC:60505-0147-8 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 01/24/2005 | 06/30/2022 |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA076471 | 01/24/2005 | 06/30/2022 |

## Labeler - Apotex Corp. (845263701)

Revised: 8/2019 Apotex Corp.