**LORATADINE ANTIHISTAMINE- loratadine tablet**
**PD-Rx Pharmaceuticals, Inc.**

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**Loratadine Tablets, 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
- 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**

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

- do not use if printed foil under cap is broken or missing
- store between 20° to 25°C (68° to 77°F)

**Inactive ingredients**

lactose monohydrate, magnesium stearate, povidone, pregelatinized starch

**Questions or comments?**

**1-800-719-9260**

**Principal Display Panel**

Compare to Claritin ®active ingredient

Loratadine Tablets, 10 mg

Antihistamine

24 Hour Relief of:

• Sneezing

• Runny Nose

• Itchy, Watery Eyes

• Itchy Throat or Nose

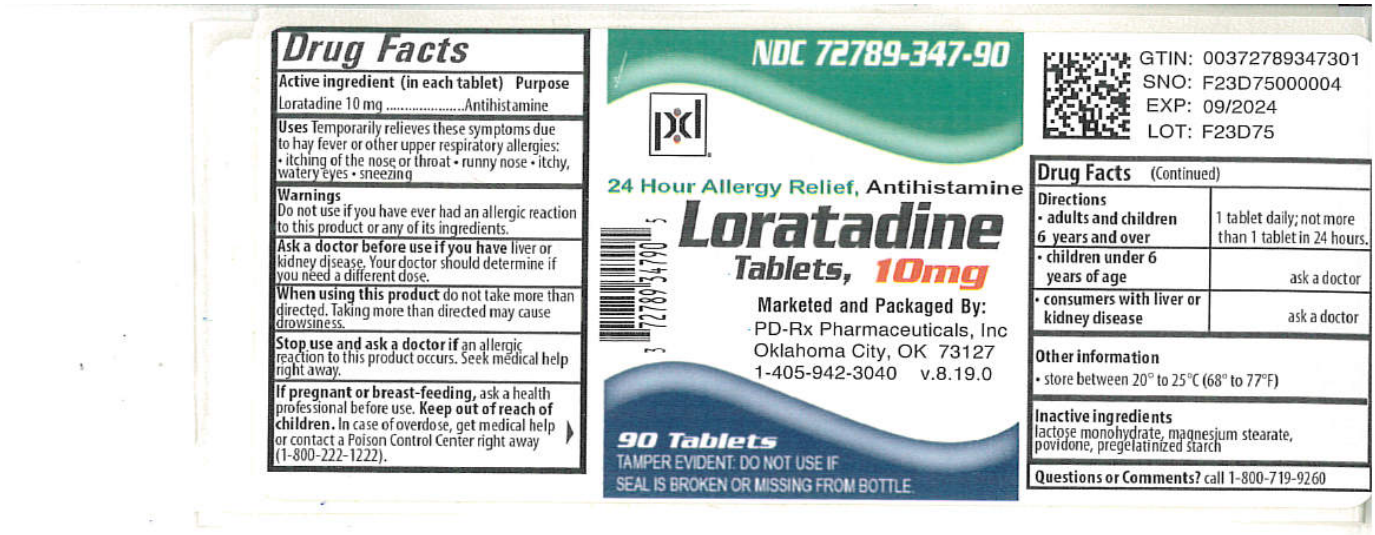
*When taken as directed. See Drug Facts Panel.

20 TABLETS. NDC 72789-347-20

30 TABLETS, NDC 72789-347-30

90 TABLETS, NDC 72789-347-90

300 TABLETS, NDC 72789-347-87




# LORATADINE ANTIHISTAMINE

loratadine tablet

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:72789-347(NDC:45802-650) |
| **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** |
| **LACTOSE MONOHYDRATE** (UNII: EWQ57Q8I5X) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **POVIDONE, UNSPECIFIED** (UNII: FZ989GH94E) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | white | **Score** | no score |
| **Shape** | OVAL | **Size** | 8mm |
| **Flavor** | | **Imprint Code** | L612 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| 1 | NDC:72789-347-30 | 30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/23/2023 | |
| 2 | NDC:72789-347-90 | 90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/23/2023 | |
| 3 | NDC:72789-347-87 | 300 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/23/2023 | |
| 4 | NDC:72789-347-20 | 20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/16/2024 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA076301 | 10/15/2008 | |

## Labeler - PD-Rx Pharmaceuticals, Inc. (156893695)

## Registrant - PD-Rx Pharmaceuticals, Inc. (156893695)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| PD-Rx Pharmaceuticals, Inc. | | 156893695 | repack(72789-347) |

Revised: 5/2024 PD-Rx Pharmaceuticals, Inc.