**LORATADINE ALLERGY RELIEF- loratadine tablet**
**Asclemed USA, Inc.**

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**Loratadine Allergy Relief**

***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**

| | |
|---|---|
| adults and children 6 years and over | 1 tablet daily; not more than 1 tablet in 24 hours |
| children under 6 years of | ask a doctor |

| | |
|---|---|
| age | ask a doctor |
| consumers with liver or kidney disease | ask a doctor |

**Other Information**

- store between 20° to 25° C (68° to 77° F)
- protect from excessive moisture
- **TAMPER EVIDENT: DO NOT USE IF BLISTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING**.

**Inactive ingredients**

corn starch, lactose monohydrate, magnesium stearate, pregelatinized starch

**Questions?**

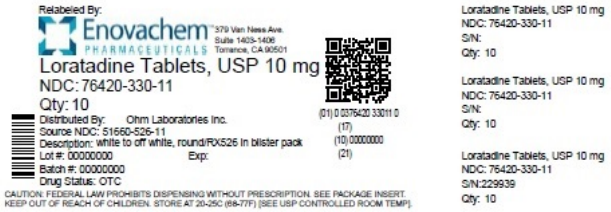
call **1-800-406-7984**

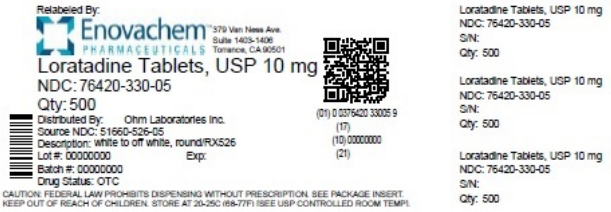
**Relabeled and Repackaged by:**

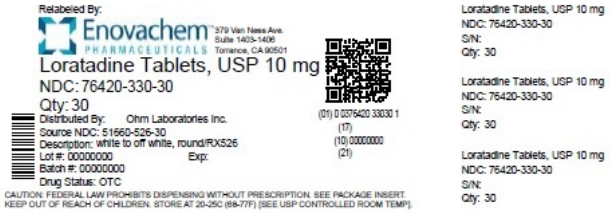
Enovachem PHARMACEUTICALS

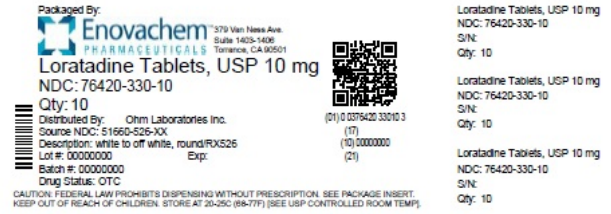
Torrance, CA 90501

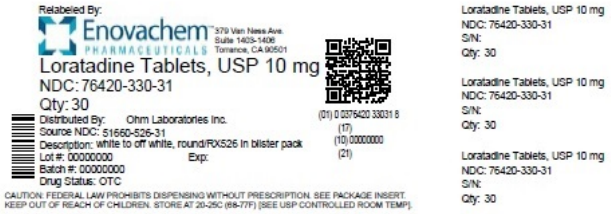
**PRINCIPAL DISPLAY PANEL**

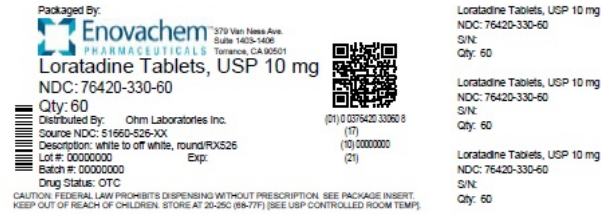


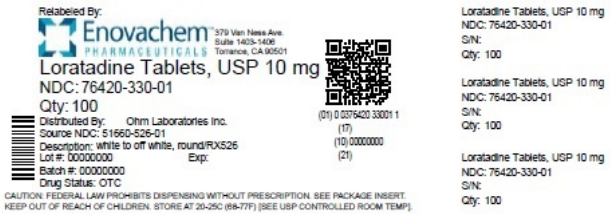



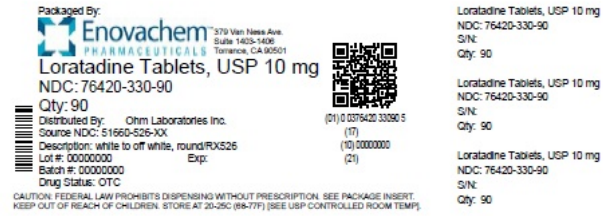



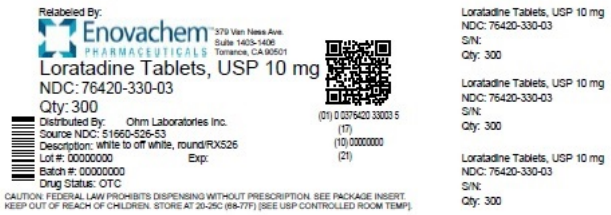




# LORATADINE ALLERGY RELIEF

loratadine tablet

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:76420-330(NDC:51660-526) |
| **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** |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |

| | |
|---|---|
| **LACTOSE MONOHYDRATE** (UNII: EWQ57Q8I5X) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | white (White to Off White) | **Score** | no score |
| **Shape** | ROUND | **Size** | 6mm |
| **Flavor** | | **Imprint Code** | RX526 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:76420-330-10 | 10 in 1 BOTTLE; Type 0: Not a Combination Product | 04/19/2025 | |
| **2** | NDC:76420-330-30 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 04/19/2025 | |
| **3** | NDC:76420-330-60 | 60 in 1 BOTTLE; Type 0: Not a Combination Product | 04/19/2025 | |
| **4** | NDC:76420-330-90 | 90 in 1 BOTTLE; Type 0: Not a Combination Product | 04/19/2025 | |
| **5** | NDC:76420-330-01 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 04/19/2025 | |
| **6** | NDC:76420-330-03 | 300 in 1 BOTTLE; Type 0: Not a Combination Product | 04/19/2025 | |
| **7** | NDC:76420-330-05 | 500 in 1 BOTTLE; Type 0: Not a Combination Product | 04/19/2025 | |
| **8** | NDC:76420-330-31 | 30 in 1 BLISTER PACK; Type 0: Not a Combination Product | 04/19/2025 | |
| **9** | NDC:76420-330-11 | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | 04/19/2025 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA076134 | 11/01/2017 | |

## Labeler - Asclemed USA, Inc. (059888437)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| ASCLEMED USA INC. DBA ENOVACHEM | | 059888437 | relabel(76420-330) , repack(76420-330) |

Revised: 4/2025 Asclemed USA, Inc.