

LORATADINE- loratadine tablet, orally disintegrating
CVS PHARMACY, INC

Loratadine Orally Disintegrating Tablets USP

Drug Facts

Active ingredient (in each tablet)

Loratadine 5 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.

Directions

- place 1 tablet on tongue; tablet disintegrates, with or without water

adults and children 6 years
and over

| |
|---|
| 1 tablet every 12 hours; not more than 2 tablets 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 the individual blister unit imprinted with Loratadine Orally disintegrating Tablet, USP is open or torn
- store between 20° to 25°C (68° to 77°F)
- use tablet immediately after opening individual blister
- complies with USP Procedure 2 for Assay and Organic Impurities and Test 2 for Disintegration

Inactive ingredients

anhydrous citric acid, mannitol, peppermint flavor, polysorbate 80, pullulan

Questions or comments?

1-877-244-9825 - Our Medical Information center shall operate between 9:00 AM to 5:00 PM EST from Monday through Friday (business hours). Queries received outside business hours shall reach voice mail and shall be attended on next business day.

Manufactured by:

Tenshi Kaizen Private Limited

Bengaluru Rural - 562112, India

Distributed by:

CVS Pharmacy, Inc.

Revised: 09/2020

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



LORATADINE

loratadine tablet, orally disintegrating

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:51316-502 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| LORATADINE (UNII: 7AJ03BO7QN) (LORATADINE - UNII:7AJ03BO7QN) | LORATADINE | 5 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | |
| PULLULAN (UNII: 8ZQ0AYU1TT) | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| MANNITOL (UNII: 3OWL53L36A) | |

Product Characteristics

| | | | |
|----------|------------|--------------|----------|
| Color | white | Score | no score |
| Shape | ROUND | Size | 12mm |
| Flavor | PEPPERMINT | Imprint Code | T5 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:51316-502-01 | 1 in 1 CARTON | 12/31/2021 | |
| 1 | | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:51316-502-02 | 2 in 1 CARTON | 12/31/2021 | |
| 2 | | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 3 | NDC:51316-502-03 | 3 in 1 CARTON | 12/31/2021 | |
| 3 | | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 4 | NDC:51316-502-04 | 4 in 1 CARTON | 12/31/2021 | |
| 4 | | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 5 | NDC:51316-502-05 | 5 in 1 CARTON | 12/31/2021 | |
| 5 | | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 6 | NDC:51316-502-06 | 6 in 1 CARTON | 12/31/2021 | |
| 6 | | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
|--------------------|--|----------------------|--------------------|

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|------|------------|------------|--|
| ANDA | ANDA212795 | 12/31/2021 | |
|------|------------|------------|--|

Labeler - CVS PHARMACY, INC (062312574)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------|---------|-----------|---------------------|
| Reed-Lane, Inc. | | 001819879 | pack(51316-502) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|--|---------|-----------|---------------------|
| Quality Packaging Specialists International, LLC | | 080629831 | pack(51316-502) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------|---------|-----------|--|
| Tenshi Kaizen Pvt Ltd | | 675478488 | analysis(51316-502) , manufacture(51316-502) , pack(51316-502) |

Revised: 1/2024

CVS PHARMACY, INC