

LORATADINE- loratadine tablet
Spirit Pharmaceuticals LLC

Loratadine Tablets, 10 mg

Active ingredient

Loratadine 10 mg

Purpose

Antihistamine

Uses

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

- runny nose
- sneezing
- itchy, water 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

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

Inactive ingredients

Lactose monohydrate, magnesium stearate, sodium starch glycolate and starch maize pregelatinized

Questions or comments?

1-888-333-9792

PRINCIPAL DISPLAY PANEL

Compare to the active ingredient in Claritin®†

NON-DROWSY*

Original Prescription Strength

Loratadine Tablets, 10 mg / Antihistamine

Indoor & Outdoor Allergies

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

365 Tablets

*When taken as directed

See Drug Facts Panel

†This product is not manufactured or distributed by Bayer Healthcare, LLC, owner of the registered trademark Claritin®.

VALUMEDS[™]

Compare to the active ingredient in Claritin[®]

NON-DROWSY*

Original Prescription Strength

ALLERGY RELIEF

Loratadine Tablets, 10 mg
Antihistamine


indoor & outdoor allergies

24 hour relief of:

- sneezing • runny nose
- itchy, watery eyes
- itchy throat or nose

365 tablets

*When taken as directed See Drug Facts Panel



Actual Size

TAMPER EVIDENT: DO NOT USE IF SEAL UNDER CAP IS MISSING, OPEN OR BROKEN

Drug Facts

Active ingredient (in each tablet) Purpose
Loratadine 10 mg.....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.

Drug Facts (continued under label)

This product is not manufactured or distributed by Bayer Healthcare, LLC, owner of the registered trademark Claritin[®].

Distributed By: Spirit Pharmaceuticals, LLC
Rockton, MA, NY 11779 ORS 09/20

ITEM# 6-4871-9



6 91036 64871 9

LOT: _____
EXP: _____

Made in India

PEEL HERE

Drug Facts (continued)

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

- store between 20° to 25°C (68° to 77°F)

Inactive ingredients
lactose monohydrate, pregelatinized starch, sodium starch glycolate, magnesium stearate

Questions or comments? 1-888-333-9792

LORATADINE

loratadine tablet

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:68210-4110 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------|
| LORATADINE (UNII: 7AJ03BO7QN) (LORATADINE - UNII: 7AJ03BO7QN) | LORATADINE | 10 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |

SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)

Product Characteristics

| | | | |
|-----------------|----------------------------|---------------------|----------|
| Color | white (White to off white) | Score | no score |
| Shape | ROUND | Size | 6mm |
| Flavor | | Imprint Code | G;10 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:68210-4110-1 | 365 in 1 BOTTLE; Type 0: Not a Combination Product | 09/11/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA210722 | 09/11/2020 | |

Labeler - Spirit Pharmaceuticals LLC (179621011)

Revised: 12/2024

Spirit Pharmaceuticals LLC