

**LORATADINE- loratadine tablet**  
**Safrel Pharmaceuticals, LLC**

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**Loratadine Tablets, 10 mg**

**ACTIVE INGREDIENT(S)**

Loratadine 10 mg

**PURPOSE**

Antihistamine

**USE(S)**

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 DOCTOR IF**

an allergic reaction to this product occurs. Seek medical help right away.

**PREGNANCY/BREASTFEEDING**

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 seal under cap, printed with "SEALED for YOUR PROTECTION" is missing, open or broken

### **Blister Foil Units**

safety sealed: do not use if the individual blister unit is open or torn

## **STORAGE**

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**

Contact 1-844-384-3723 Mon-Fri 9:00 AM to 4:30 PM EST.

## **PRINCIPAL DISPLAY PANEL**

Compares to the active ingredient in CLARATIN® Tablets\*

**Safrel®**  
Non-Drowsy 24 Hour  
**Allergy Relief**  
indoor & outdoor allergies

Loratidine Tablets, USP  
Antihistamine

10 mg

24 hour relief of:

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

300 Tablets

NDC 71309-007-03

**Drug Facts**

**Active ingredient (in each tablet)**  
Loratidine, USP 10 mg.....Antihistamine

**Purpose**

**Uses**

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
  - runny nose
  - sneezing
  - itchy, watery eyes
  - itchy 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.

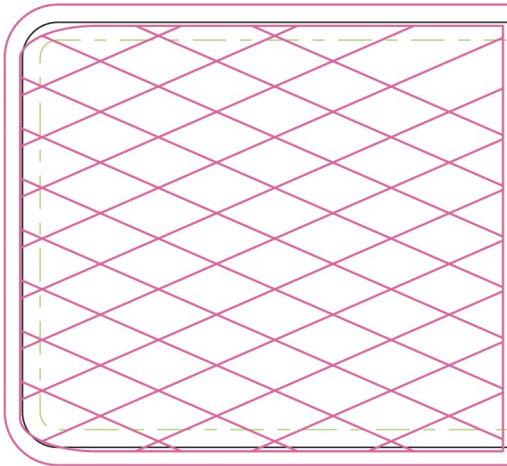
**DRUG FACTS CONTINUED on back of the label**

**DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING**

Distributed By: Safrel Pharmaceuticals  
Bridgewater, NJ 08807 USA  
www.safrelpharma.com



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 (1-800-222-1222) right away.

**Directions**

<b>Adults and children 6 years and over</b>	1 tablet daily; not more than 1 tablet in 24 hours
<b>Children under 6 years</b>	ask a doctor
<b>Consumers with liver or kidney disease</b>	ask a doctor

**Other information**

- protect from moisture
- store at 25°C (77°F) excursions permitted between 15°-30°C (59°-86°F)

**Inactive ingredients**

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

**Questions or Comments? 1-844-384-3723**

STOP PEELING

# LORATADINE

loratadine tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71309-007
<b>Route of Administration</b>	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

<b>Color</b>	white (White to off white)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	6mm
<b>Flavor</b>		<b>Imprint Code</b>	G;10
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71309-007-03	300 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210722	01/01/2020	

**Labeler** - Safrel Pharmaceuticals, LLC (080566287)

Revised: 10/2020

Safrel Pharmaceuticals, LLC