

LORATADINE- loratadine tablet
Apotex Corp.

Drug Facts

Active ingredient (in each tablet)

Loratadine, USP 10

Purpose

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.

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 2° and 30°C (36° and 86°F)
- do not use if seal under bottle cap is broken or missing
- protect from excessive moisture

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose

Questions or comments?

Call 1-800-706-5575, weekdays, 8:30am - 5:00pm Eastern Standard Time

Principal Display Panel

Just Well NDC 60505-4649-3

Non-Drowsy*

Loratadine Tablets, USP 10 mg

Antihistamine

Indoor & Outdoor Allergies

24 hour

Relief of:

Sneezing Runny Nose

Itchy, Watery Eyes

Itchy Throat or Nose

justwell.® ***Compare to the active ingredient of Claritin®*

Loratadine Tablets, USP 10 mg

Antihistamine / Original Prescription Strength

Indoor & Outdoor Allergies

RELIEF OF:
Sneezing; Runny Nose; Itchy, Watery Eyes; Itchy Throat or Nose

*When Taken as directed. See Drug Facts Panel.

365 Tablets

24 Hour Allergy

Non-Drowsy*

Drug Facts
Active ingredient (in each tablet)
Loratadine, USP 10 mg.....Antihistamine

Purpose
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. **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 ■ safety sealed: do not use if induction seal, with "Lift N Peel" tab, under cap is broken or missing ■ store between 2° and 30°C (36° and 86°F) ■ protect from excessive moisture

Inactive ingredients colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose

Questions or comments? Call 1-800-706-5575, weekdays, 8:30am - 5:00pm Eastern Standard Time

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

DISTRIBUTED BY: APOTEX CORP. WESTON, FLORIDA 33326
MADE IN CANADA

Principal Display Panel

Just Well NDC 60505--4649-3

Non-Drowsy*

Loratadine Tablets, USP 10 mg

Antihistamine

Indoor & Outdoor Allergies

24 hour Relief of:

Sneezing

Runny Nose

Itchy, Watery Eyes

Itchy Throat or Nose



LORATADINE

loratadine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60505-4649
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL	Size	8mm
Flavor		Imprint Code	LOR;10;APO
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60505-4649-3	365 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2017	10/31/2021

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076471	11/21/2017	10/31/2021

Labeler - Apotex Corp. (845263701)

Revised: 8/2019

Apotex Corp.