

**LORATADINE- loratadine tablet  
AvPAK**

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**Loratadine Tablets USP 10 mg**

***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 (1-800-222-1222) 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
- store at 20° to 25°C (68° to 77°F)
- protect from excessive moisture

**Inactive ingredients**

lactose monohydrate, magnesium stearate, pregelatinized starch (maize), sodium starch glycolate.

**Questions or comments?**

call **1-855-361-3993**

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 10 mg (45 Tablets Bottle)**

<b>Drug Facts</b>	
<b>Active ingredient (in each tablet)</b> Loratadine USP 10 mg	<b>Purpose</b> Antihistamine
<b>Uses</b> 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	
<b>Warnings</b> Do not use if you have ever had an allergic reaction to this product or any of its ingredients. <b>Ask a doctor before use if you have liver or kidney disease.</b> Your doctor should determine if you need a different dose. <b>When using this product do not take more than directed.</b> Taking more than directed may cause drowsiness. <b>Stop use and ask a doctor if an allergic reaction to this product occurs.</b> Seek medical help right away. <b>If pregnant or breast-feeding,</b> ask a health professional before use. <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.	
<b>Directions</b>	
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
<b>Other information</b> • safety sealed; do not use if the individual blister unit is open or torn • store at 20° to 25°C (68° to 77°F) • protect from excessive moisture	
<b>Inactive ingredients</b> lactose monohydrate, magnesium stearate, pregelatinized starch (maize), sodium starch glycolate.	
<b>Questions or comments?</b> call 1-855-361-3993	

## Loratadine Tablets USP

10 mg

Antihistamine  
Indoor & Outdoor Allergies

\*This product is not manufactured or distributed by Bayer Healthcare LLC distributor of Claritin®.

Manufactured for:  
AvKARE, Inc.  
Pulaski, TN 38478

Made in India  
Code: TS/DRUGS/22/2009



NDC 50268-489-15

\*Compare to the active ingredient in Claritin®

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

\*When taken as directed See Drug Facts Panel.

50 Tablets (5 X 10) Unit Dose

**AVPAK™**  
A PRODUCT OF AVKARE

## LORATADINE

loratadine tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50268-489
<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)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

### Product Characteristics

Color	Score	Shape	Size	Flavor	Imprint Code	Contains
white (White to Off-white)	no score	ROUND	6mm		39;L	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

<b>1</b>	NDC:50268-489-15	50 in 1 BOX	05/28/2019	
<b>1</b>	NDC:50268-489-11	1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA208314	05/28/2019	

**Labeler - AvPAK (832926666)**

Revised: 1/2024

AvPAK