

**ALLERGY RELIEF- loratadine tablet**  
**AAA PHARMACEUTICAL, INC.**

-----  
**RES-1193A-2021-1108**

***Drug Facts***

**Active ingredient (in each tablet)**

Loratadine 10 mg

**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 (1-800-222-1222).

**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)
- retain carton for complete product information and warnings

### Inactive ingredients

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

### PRINCIPAL DISPLAY PANEL

Restore U

NDC 57344-193-17

24 hour

Non-Drowsy\*

†Compare to the active ingredient in Claritin® Tablets

Allergy Relief

Loratadine Tablets, 10 mg

Antihistamine

Indoor and Outdoor Allergies

Original Prescription Strength

\*When taken as directed. See Drug Facts Panel.

Actual Size

30 TABLETS

**RESTORE U**  
NDC 57344-193-17  
24 hour Non-Drowsy\*  
†Compare to the active ingredient in Claritin® Tablets  
**Allergy Relief**  
Loratadine Tablets, 10 mg  
Antihistamine  
Indoor and Outdoor Allergies  
Original Prescription Strength  
\*When taken as directed. See Drug Facts Panel.  
Actual Size  
**30 TABLETS**

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

**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:  
 ■ itchy, watery eyes  
 ■ runny nose  
 ■ 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 (1-800-222-1222).

**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 20-25°C (68-77°F)

**Inactive ingredients** lactose monohydrate, magnesium stearate, pregelatinized starch (maize), sodium starch glycolate

L1193A17RES\_R0  
0 99581 91186 17  
Distributed by: AAA Pharmaceutical, Inc.  
Lumberton, NJ 08048 • 1-844-705-4384  
Made in India  
†This product is not manufactured or distributed by Bayer Healthcare LLC, distributor of Claritin® Tablets

**ALLERGY RELIEF**

loratadine tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:57344-193
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
LORATADINE (UNII: 7AJ03BO7QN) (LORATADINE - UNII:7AJ03BO7QN)	LORATADINE	10 mg

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
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:57344-193-17	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/14/2020	
2	NDC:57344-193-19	1 in 1 CARTON	04/29/2022	
2		30 in 1 BOTTLE, PLASTIC; 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	ANDA210722	08/14/2020	

**Labeler** - AAA PHARMACEUTICAL, INC. (181192162)