

LORATADINE- loratadine tablet
PLD Acquisitions LLC DBA Avéma Pharma Solutions

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
- 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 the printed bottle seal is open or torn
- store at 20°-25°C (68°-77°F) (see USP Controlled Room Temperature)

Inactive ingredients

lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium starch glycolate

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9 AM-5 PM EST

Principal Display Panel

†Compare to the active ingredient in Claritin®

Loratadine tablets, USP

Antihistamine

10 mg

Non-drowsy*

Indoor & outdoor allergies

24-hour relief of

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

100 Tablets

*When taken as directed. See Drug Facts panel

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

†This product is not manufactured or distributed by Bayer HealthCare LLC, distributor of Claritin®

Manufactured by:

Avema Pharm Solutions

10400 NW 29th Terrace, Miami, FL 33172

Package Label

NDC 63548-0753-1

¹Compare to the active ingredient in Claritin®

Loratadine tablets, USP
Antihistamine

10 mg

Non-drowsy*

Indoor & outdoor allergies

24-hour relief of

- ✓ Sneezing
- ✓ Itchy, watery eyes
- ✓ Runny nose
- ✓ Itchy throat or nose



Actual Size

100 Tablets

*When taken as directed. See Drug Facts panel.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

Drug Facts	Drug Facts (continued under label)
<p>Purpose</p> <p>Active ingredient (in each tablet) Loratadine, USP 10 mg.....Antihistamine</p> <p>Uses Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: <ul style="list-style-type: none"> ■ runny nose ■ sneezing ■ itchy, watery eyes ■ itching of the nose or throat </p> <p>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.</p>	<p>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</p> <p>Other information ■ safety seal†: do not use if the printed bottle seal is open or torn ■ store at 20°-25°C (68°-77°F) (see USP Controlled Room Temperature)</p> <p>Inactive ingredients lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium starch glycolate</p> <p>Questions or comments? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST</p>

[†]This product is not manufactured or distributed by Bayer HealthCare LLC, distributor of Claritin®.

Manufactured by:
Avéna Pharma Solutions
10400 NW 29th Terrace, Miami, FL 33172



PLD-A Lot No.: Exp. Date:



Drug Facts (continued)	
<p>When using this product, do not take more than directed. Taking more than directed may cause drowsiness.</p> <p>Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p>	
Directions	<p>adults and children 6 years and over: 1 tablet daily, not more than 1 tablet in 24 hours.</p> <p>children under 6 years of age: ask a doctor</p> <p>consumers with liver or kidney disease: ask a doctor</p>
Other information	<p>■ safety seal†: do not use if the printed bottle seal is open or torn</p> <p>■ store at 20°-25°C (68°-77°F) (see USP Controlled Room Temperature)</p>
Inactive ingredients	lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium starch glycolate
Questions or comments?	Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Loratadine 10 mg Tablets

LORATADINE

loratadine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63548-0753
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: EWQ57Q815X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	WHITE	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	GG296
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63548-0753-0	300 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/30/2018	
2	NDC:63548-0753-1	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/30/2018	
3	NDC:63548-0753-3	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/30/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075209	10/30/2018	

Labeler - PLD Acquisitions LLC DBA Avéma Pharma Solutions (804087794)

Revised: 12/2019

PLD Acquisitions LLC DBA Avéma Pharma Solutions