

**365 WHOLE FOODS MARKET LORATADINE - loratadine tablet**  
**Whole Foods Market, Inc.**

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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 1-855-274-4122**

**DISTRIBUTED BY:**

WHOLE FOODS MARKET

550 BOWIE STREET, AUSTIN, TX 78703

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**[www.wholefoodsmarket.com](http://www.wholefoodsmarket.com)**

**PRODUCT OF INDIA**

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 10 mg (30 Tablets Container Label)**

**365**

WHOLE FOODS

MARKET

NDC 42681-0053-1

Non-  
Drowsy\*

Antihistamine

Allergy Relief

Loratadine  
Tablets USP, 10mg

Indoor & Outdoor Allergies

\*WHEN TAKEN AS DIRECTED. SEE DRUG FACTS PANEL.

30

TABLETS

<p><b>365</b> WHOLE FOODS MARKET</p> <p>Non- Drowsy*</p> <p><b>Antihistamine</b></p> <p><b>Allergy Relief</b></p> <p>Loratadine Tablets USP, 10mg</p> <p>Indoor &amp; Outdoor Allergies</p> <p><b>30</b> TABLETS</p> <p><small>*WHEN TAKEN AS DIRECTED. SEE DRUG FACTS PANEL.</small></p>	<p>NDC 42681-0053-1</p> <p><b>Drug Facts</b></p> <p><b>Active ingredient (in each tablet)</b> Loratadine USP 10 mg.</p> <p><b>Purpose</b> Antihistamine</p> <p><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</p> <p><b>Warnings</b> 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><b>When using this product</b> 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.</p> <p><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</p> <p><b>Other information</b> ■ 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° (68° to 77°) ■ protect from excessive moisture</p> <p><b>Inactive ingredients</b> lactose monohydrate, magnesium stearate, pregelatinized starch (maize), sodium starch glycolate.</p> <p><b>Questions or comments?</b> call 1-855-274-4722</p> <p><b>DISTRIBUTED BY:</b> WHOLE FOODS MARKET 550 BOWIE STREET, AUSTIN, TX 78703 ©2025 WHOLE FOODS MARKET LP, INC. <a href="http://www.wholefoodsmarket.com">www.wholefoodsmarket.com</a></p> <p><b>PRODUCT OF INDIA</b></p>	<p>P1436150</p> <p>Unvarnished Zone (dotted line not for printing) 28.5 x 13 mm</p>
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PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 10 mg (30 Tablets Container Carton)

NDC 42681-0053-1

365

WHOLE FOODS

MARKET

Antihistamine

Allergy Relief

Loratadine  
Tablets USP, 10mg

\*\*Compare to the Active Ingredient in Claritin®

## **Indoor & Outdoor Allergies**

Sneezing | Runny nose

Itchy, Watery Eyes | Itchy Throat or Nose

***Non-Drowsy\****

***24 Hour***

***Relief***

**ACTUAL SIZE**

\*WHEN TAKEN AS DIRECTED. SEE DRUG FACTS PANEL.

**30**

**TABLETS**



## 365 WHOLE FOODS MARKET LORATADINE

loratadine tablet

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42681-0053
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: EWQ57Q8I5X)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
STARCH, CORN (UNII: O8232NY3SJ)				
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)				
Product Characteristics				
Color	WHITE (White to Off-white)	Score	no score	
Shape	ROUND	Size	6mm	
Flavor		Imprint Code	39;L	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42681-0053-1	1 in 1 CARTON	04/25/2025	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:42681-0053-2	1 in 1 CARTON	04/25/2025	
2		90 in 1 BOTTLE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA208314		04/25/2025	

**Labeler -** Whole Foods Market, Inc. (196175616)

**Registrant -** Aurohealth LLC (078728447)

Establishment			
Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(42681-0053) , MANUFACTURE(42681-0053)