

LORATADINE - loratadine capsule, liquid filled
Aurohealth LLC

Drug Facts

Active ingredient

(in each capsule)

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 (1-800-222-1222) right away.

Directions

adults and children 6 years and over	1 capsule daily; not more than 1 capsule in 24 hours
children under 6 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

Other information

- do not use if the individual blister unit is open or torn
- store between 20° to 25°C (68° to 77°F)
- protect from freezing
- FDA approved dissolution test specifications differ from USP

Inactive ingredients

Gelatin, glycerin, glyceryl monocaprylocaprate, hypromellose, isopropyl alcohol, Neelicert FD&C Blue No.1, polysorbate 80, povidone, propylene glycol, purified water, sorbitol sorbitan solution and titanium dioxide.

Questions or comments?

call **1-855-274-4122** (Monday – Friday 8:30 AM to 5:00 PM EST)

Distributed by:

AUROHEALTH LLC

279 Princeton-Hightstown Road
East Windsor, NJ 08520

Made in India

Code: TS/DRUGS/22/2009

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 10 mg (10 Capsule Blister Carton)

AUROHEALTH

NDC 58602-818-83

Compare to the active ingredient

in Claritin® Liqui-Gels®†

Non-Drowsy*

Loratadine Capsules USP 10 mg

Antihistamine

Indoor & Outdoor Allergies

Relief of:

- *Sneezing*
- *Runny Nose*
- *Itchy, Watery Eyes*
- *Itchy Throat or Nose*

24 HOUR

10 Liquid-Filled Capsules

*When taken as directed.

See Drug Facts Panel.

Drug Facts		Drug Facts (continued)	
Active ingredient (in each capsule) Loratadine USP 10 mg.....Antihistamine	Purpose Antihistamine	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.	
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		Directions	
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.		adults and children 6 years and over	1 capsule daily; not more than 1 capsule in 24 hours
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		Questions or comments? call 1-855-274-4122 (Monday – Friday 8:30 AM to 5:00 PM EST)	

Loratadine Capsules USP 10 mg
Antihistamine
 Indoor & Outdoor Allergies
 10 CAPSULES FOR 10 DAYS OF RELIEF



AUROHEALTH NDC 58602-818-83
 Compare to the active ingredient in Claritin® Liqui-Gels®†

Non-Drowsy*
Loratadine Capsules USP 10 mg
Antihistamine
Indoor & Outdoor Allergies

Relief of:

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose

24 HOUR

10 Liquid-Filled Capsules

*When taken as directed. See Drug Facts Panel.

Distributed by: AUROHEALTH LLC, 279 Princeton-Hightstown Road, East Windsor, NJ 08520
 Made in India
 Code: TS/DRUGS/22/2009
 †This product is not manufactured or distributed by Bayer Healthcare LLC owner of the registered trademark Claritin®, or Catalent Pharma Solutions, Inc., owner of the registered trademark Liqui-Gels®

No Varnish Zone

* Batch & Expiry: will be over coded during the production time

loratadine capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-818
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
GELATIN TYPE B BOVINE (160 BLOOM) (UNII: 1T8387508X)	
GLYCERIN (UNII: PDC6A3C00X)	
GLYCERYL MONO AND DICAPRYLOCAPRATE (UNII: U72Q2I8C85)	
HYPROMELLOSE 2910 (3 MPA.S) (UNII: 0VUT3PMY82)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONE K30 (UNII: U725QWY32X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BLUE	Score	no score
Shape	OVAL	Size	11mm
Flavor		Imprint Code	LR10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-818-83	1 in 1 CARTON	03/24/2023	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:58602-818-67	2 in 1 CARTON	03/24/2023	
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:58602-818-84	3 in 1 CARTON	03/24/2023	
3		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

4	NDC:58602-818-08	4 in 1 CARTON	03/24/2023	
4		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:58602-818-05	5 in 1 CARTON	03/24/2023	
5		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211900	03/24/2023	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(58602-818) , MANUFACTURE(58602-818)

Revised: 3/2023

Aurohealth LLC