

**LORATADINE 10 MG- loratadine tablets usp, 10 mg tablet
TIME CAP LABORATORIES, INC.**

Timely 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 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

- **Tamper evident: do not use this product if the imprinted foil seal over the mouth of the bottle is cut, torn, broken or missing.**
- store between 20° to 25° C (68° to 77° F)
- FDA approved dissolution test specifications differ from USP

Inactive ingredient

colloidal silicon dioxide, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium starch glycolate

Questions or comments?

Call **1-877-290-4008**

Adhesive Area

Drug Facts (continued)

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NDC 49483-732-65



†Compare to the active ingredient in Claritin® Tablets

Original Prescription Strength
Loratadine Tablets USP, 10 mg

Antihistamine | Non-Drowsy*
Indoor & Outdoor Allergies

24 Hour Relief of:
• Sneezing • Itchy, Watery Eyes
• Itchy Throat or Nose • Runny Nose

365 TABLETS

*When taken as directed. See Drug Facts Panel.



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Drug Facts (continued under label)

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

Distributed by:

- 1 Time-Cap Labs, Inc.,
- 7 Michael Avenue,
- 4 Farmingdale, NY 11735

Made in India

732R 0125



Varnish Omit Area

LOT:
EXP.:

PEEL HERE (with arrow pointing to the bottom edge of the label)

LORATADINE 10 MG

loratadine tablets usp, 10 mg tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49483-732
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LORATADINE (UNII: 7AJ03B07QN) (LORATADINE - UNII: 7AJ03B07QN)	LORATADINE	10 mg

Inactive Ingredients

Ingredient Name	Strength
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK)	

LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)

Product Characteristics

Color	white (White to off-white)	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	92
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-732-65	365 in 1 BOTTLE; Type 0: Not a Combination Product	01/25/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA219223	01/25/2025	

Labeler - TIME CAP LABORATORIES, INC. (037052099)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(49483-732)

Revised: 1/2025

TIME CAP LABORATORIES, INC.