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

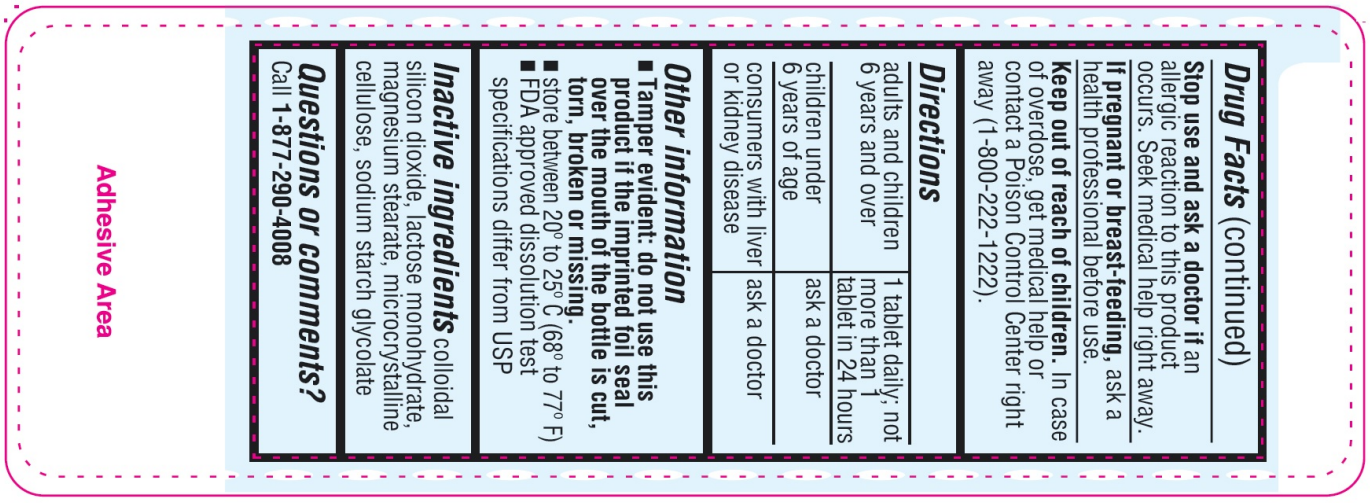
- **Tamper evident: do not use this product if the imprinted foil seal over the mouth of the bottle is cut, torn, broken or missing.**
- store between 20º to 25º C (68º to 77º F)
- FDA approved dissolution test specifications differ from USP

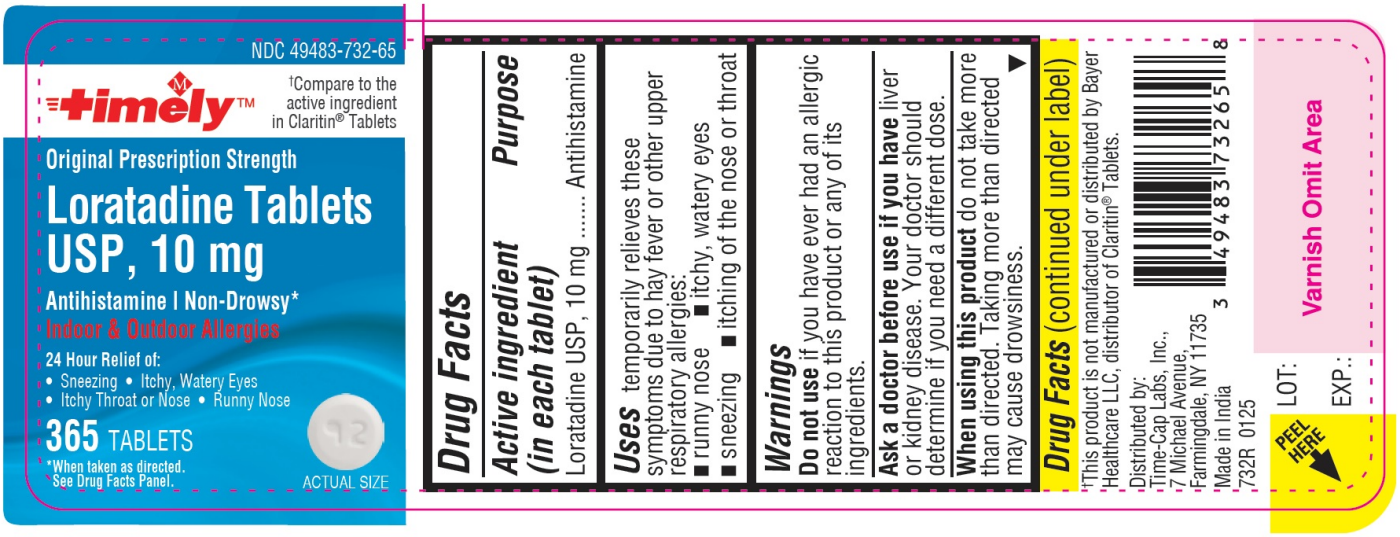
Inactive ingredient

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

Questions or comments?

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





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: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN)	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.