

**LORATADINE - loratadine capsule, liquid filled**  
**MARKSANS PHARMA LIMITED**

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**Loratadine Liquid Filled Capsules, 10 mg (OTC)**

**Drug Facts**

**Active ingredient (in each capsule)**

Loratadine 10mg

**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**

**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 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.

**Inactive ingredients**

FD&C blue no. 1, gelatin, mono and diglyceride of caprylic/capric acid, pharmaceutical ink, polysorbate 80, povidone, purified water, sorbitol sorbitan solution.

***Questions or comments?***

Call at 1-877-376-4271

**Other information**

- Store at 20°-25°C (68°-77°F)
- protect from freezing.
- **Safety sealed: do not use if the individual blister unit imprinted with Loratadine Capsules is open or torn.**

**Manufactured for****Time-Cap Labs. Inc.**

7 Michael Avenue,  
Farmingdale,  
NY 11735, USA

**Manufactured by**

**Marksans Pharma Ltd.**  
 Plot No. L-82, L-83,  
 Verna Indl. Estate,  
 Verna, GOA 403722, India.

## Principal Display Panel

NDC# 25000-021-13  
 Loratadine Capsules, 10 mg  
 600 counts Bottle Label

NDC 25000-021-13

**Non-Drowsy\***

# Loratadine Capsules

loratadine 10 mg/  
antihistamine

**Indoor & Outdoor Allergies**

\* When taken as directed.  
See Drug Facts Panel.

**24 HOUR**

**Relief of:**

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

**600 LIQUID-FILLED CAPSULES**

LOT: EXP:

3 25000 021 13 9

<b>Drug Facts</b>	<b>Drug Facts (continued)</b>
<p><b>Active ingredient (in each capsule) Purpose</b>            Loratadine 10 mg.....Antihistamine</p>	<p><b>Warnings</b>  <b>Do not use</b> if you have ever had an allergic reaction to this product or any of its ingredients.</p>
<p><b>Uses</b>            temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:</p> <ul style="list-style-type: none"> <li>■ runny nose ■ sneezing ■ itchy, watery eyes</li> <li>■ itching of the nose or throat</li> </ul>	<p><b>Ask a doctor before use if you have</b> 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.</p>

<b>Drug Facts (continued)</b>	<b>Drug Facts (continued)</b>
<p><b>Stop use and ask a doctor if</b> an allergic reaction to this product occurs. Seek medical help right away.</p>	<p><b>Directions</b>  <b>Adults and children 6 years and over:</b> 1 capsule daily; Not more than 1 capsule in 24 hours. <b>Children under 6 years of age :</b> ask a doctor.  <b>Consumers with liver or kidney disease :</b> ask a doctor</p>
<p><b>If pregnant or breast-feeding</b> ask a health professional before use.</p>	

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**Other information**

- Store at 20°-25°C (68°-77°F)
- protect from freezing.
- **Safety Sealed** : do not use if safety seal is open or torn.

**Drug Facts (continued)**

**Inactive ingredients**

FD&C blue no.1, gelatin, mono and diglyceride of caprylic / capric acid, pharmaceutical ink, polysorbate 80, povidone, purified water, sorbitol sorbitan solution.

**Questions or comments?**

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Plot No. L-82, L-83,  
Verna Indl. Estate, Verna,  
GOA - 403 722, India.

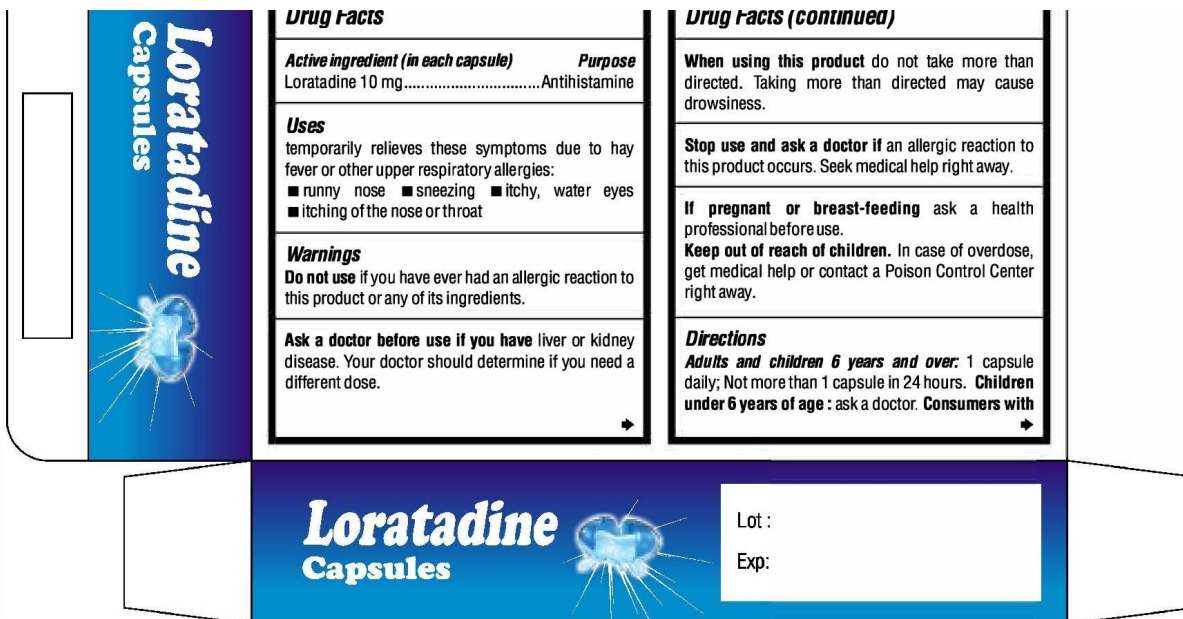
Mfg. Lic. No. : GO/Drugs/515

R102/16



NDC# 25000-021-34  
Loratadine Capsules, 10 mg  
28 counts Blister Pack





## PANEL 2

<b>Drug Facts (continued)</b> liver or kidney disease : ask a doctor		Manufactured for: <b>Time-Cap Labs, Inc.</b> 7 Michael Avenue, Farmingdale, NY 11735, USA  Manufactured by: <b>Marksans Pharma Ltd.</b> Plot No. L-82, L-83, Verna Indl. Estate, Verna, GOA - 403 722, India.  Mfg. Lic. No. : GQ/Drugs/515
<b>Other information</b> ■ Store at 20°-25°C (68°-77°F) ■ protect from freezing. ■ <b>Safety sealed: do not use if the individual blister unit imprinted with Loratadine Capsules is open or torn.</b>		
<b>Inactive ingredients</b> FD&C blue no.1, gelatin, mono and diglyceride of caprylic / capric acid, pharmaceutical ink, polysorbate 80, povidone, purified water, sorbitol sorbitan solution.		
<b>Questions or comments?</b> Call at 1-877-376-4271		

## PRINCIPAL DISPLAY PANEL

NDC# 25000-021-36  
 Loratadine Capsules, 10 mg  
 3x10 carton Label





## PANEL 2

<b>Drug Facts (continued)</b> liver or kidney disease : ask a doctor <b>Other information</b> ■ Store at 20°-25°C (68°-77°F) ■ protect from freezing. ■ <b>Safety sealed: do not use if the individual blister unit imprinted with Loratadine Capsules is open or torn.</b> <b>Inactive ingredients</b> FD&C blue no.1, gelatin, mono and diglyceride of caprylic / capric acid, pharmaceutical ink, polysorbate 80, povidone, purified water, sorbitol sorbitansolution. <b>Questions or comments?</b> Call at 1-877-376-4271		Manufactured by: <b>Time-Cap Labs, Inc.</b> 7 Michael Avenue, Farmingdale, NY 11735, USA  Manufactured by: <b>Marksans Pharma Ltd.</b> Plot No. L-82, L-83, Verna Indl. Estate, Verna, GOA - 403 722, India. Mfg. Lic. No. : GO/Drugs/515
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<b>Description :</b> NDC 25000-021-36 Loratadine Capsules 30's Carton <b>File # :</b> NDC 25000-021-36 <b>Version :</b> R209/20 <b>Date :</b> 17/09/2020 <b>Size :</b> 100.00(L) X 60.00(H) X 20.00(W) mm		<b>Color scheme :</b> ■ PANTONE 485 C ■ PANTONE 273 C ■ PANTONE Process Cyan C ■ PANTONE 7406 C ■ BLACK
<b>Labeling Format Information :</b> <b>Fonts :</b> Wnd. Cooper black, SW Condensed, Bold, Bold Italic. <b>Drug Facts :</b> 8.25 pt. <b>Header :</b> 7.00 pt. <b>Subheader :</b> 6.00 pt. <b>Body Text :</b> 6.00 pt. <b>Drug Facts (Continued) :</b> 8.25 pt. <b>Horizontal Scale :</b> 70%		<b>Leading :</b> 6.00 pt. <b>Header :</b> 5.00 pt. <b>Barlines :</b> 2.50 pt. <b>Hairlines :</b> 0.50 pt. <b>Average Kerning :</b> 0

# LORATADINE

loratadine capsule, liquid filled

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:25000-021
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
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
CAPRIC ACID (UNII: 4G9EDB6V73)	
POVIDONE K30 (UNII: U725QWY32X)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SORBITAN (UNII: 6O92ICV9RU)	

## Product Characteristics

Color	BLUE (Light Blue)	Score	no score
Shape	OVAL (oval shaped)	Size	3mm
Flavor		Imprint Code	21
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:25000-021-08	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2016	
2	NDC:25000-021-13	600 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2016	
3	NDC:25000-021-46	8 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2016	
4	NDC:25000-021-34	28 in 1 BLISTER PACK; Type 0: Not a Combination Product	10/01/2016	
5	NDC:25000-021-21	4 in 1 BOX	10/01/2016	
5		7500 in 1 BAG; Type 0: Not a Combination Product		
	NDC:25000			

6	NDC: 25000-021-36	3 in 1 CARTON	10/17/2020	
6		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	ANDA206214		10/01/2016	

**Labeler -** MARKSANS PHARMA LIMITED (925822975)

## Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	MANUFACTURE(25000-021)

Revised: 11/2021

MARKSANS PHARMA LIMITED