

LORATADINE - loratadine capsule, liquid filled
MARKSANS PHARMA LIMITED

Loratadine

ACTIVE INGREDIENT(S)

Loratadine 10mg

PURPOSE

Antihistamine

USE(S)

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies

- runny nose
- sneezing
- itchy, water 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.

ASK A DOCTOR OR PHARMACIST BEFORE USE IF

WHEN USING THIS PRODUCT

do not take more than directed. Taking more than directed may cause drowsiness.

STOP USE AND ASK DOCTOR IF

an allergic reaction to this product occurs. Seek medical help right away

OTHER REQUIRED WARNINGS

PREGNANCY/BREASTFEEDING

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, gelatine, mono and diglyceride of caprylic/capric acid, pharmaceutical ink, polysorbate 80, povidone, purified water, sorbitol, sorbitan solution.

STORAGE

Store at 20°-25°C (68°-77°F).

Protect from freezing.

Safely sealed: do not use if the safety seal is open or torn.

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: _____

Drug Facts	Drug Facts (continued)
Active ingredient (in each capsule) Purpose Loratadine 10 mg.....Antihistamine	Warnings Do not use if you have ever had an allergic reaction to this product or any of its ingredients.
Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ runny nose ■ sneezing ■ itchy, water eyes ■ itching of the nose or throat	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.

Drug Facts (continued)	Drug Facts (continued)
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 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)	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 - 403 722, India.
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.	Mfg. Lic. No. : GO/Drugs/515
Questions or comments? Call at 1-877-376-4271	R102/16 

PRINCIPAL DISPLAY PANEL

NDC# 25000-021-34

Loratadine Capsules, 10 mg

28 counts Blister Pack



PANEL 2

<p>Drug Facts (continued)</p> <p>Liver or kidney disease: ask a doctor</p>	
<p>Other information</p> <ul style="list-style-type: none"> 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. 	
<p>Inactive ingredients</p> <p>FD&C blue no.1, gelatin, mono and diglyceride of caprylic / capric acid, pharmaceutical ink, polysorbate 80, povidone, purified water, sorbitol sorbitan solution.</p>	
<p>Questions or comments? Call at 1-877-376-4271</p>	
<p>Manufactured by: Time-Cap Labs, Inc. 7 Michael Avenue, Farmingdale, NY 11735, USA</p> <p>Manufactured by: Marksans Pharma Ltd. Plot No. L-82, L-83, Verna Indl. Estate, Verna, GOA - 403 722, India.</p> <p>Mfg. Lic. No.: GO/Drugs/515</p>	
<p>H102/16</p>	

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: 7AJ03BO7QN) (LORATADINE - UNII:7AJ03BO7QN)	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		

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: 10/2016

MARKSANS PHARMA LIMITED