

LORATADINE 10MG - loratadine 10mg tablet
MARKSANS PHARMA LIMITED

Loratadine Tablets USP 10mg

ACTIVE INGREDIENT(S)

Active ingredient (in each tablet)

Loratadine USP, 10 mg

PURPOSE

Purpose

Antihistamine

USE(S)

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

Warnings

DO NOT USE

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

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

When using this product do not take more than directed. Taking more than directed may cause drowsiness.

STOP USE AND ASK DOCTOR IF

Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.

PREGNANCY/BREASTFEEDING

If pregnant or breast-feeding, ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN

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

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 REQUIRED WARNINGS

Other information

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

Inactive ingredients

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

Questions or comments?

Questions or comments? Call **1-877-376-4271** (weekdays 9 AM to 5 PM)

Manufactured for:
Time-Cap Labs, Inc.
7 Michael Avenue,

Farmingdale,
NY 11735

Manufactured by:
Marksans Pharma Ltd.
Plot No. L-82, L-83
Verna Indl. Estate
Verna, Goa-403722

Made in India

PRINCIPAL DISPLAY PANEL

NDC: 25000-092-81
Loratadine Tablets USP, 10 mg
14's count Carton

Varnish Omit

ACTUAL SIZE

PACKAGE NOT CHILD-RESISTANT

*When taken as directed. See Drug Facts Panel.

14 TABLETS

- ✓ Sneezing
- ✓ Itchy, watery eyes
- ✓ Runny nose
- ✓ Itchy throat or nose

24 HOUR

**Relief of:
Indoor & Outdoor Allergies**

Loratadine Tablets USP, 10 mg

Non-Drowsy*

Original Prescription Strength



NDC 25000-092-81
Compare to the active ingredient
in Claritin® Tablets††

Varnish Omit

Varnish Omit

Drug Facts

**Active ingredient
(in each tablet)**

Purpose

Loratadine USP, 10mg.....Antihistamine ▶

Drug Facts (continued)

Uses

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

- runny nose
- itchy, watery eyes
- sneezing

Drug Facts (continued)

- 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. ▶

Drug Facts (continued)

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 if the individual blister unit is open or torn**

Drug Facts (continued)

- store between 20° to 25° C (68° to 77° F)
- FDA approved dissolution test specifications differ from USP

Inactive ingredients colloidal silicon dioxide, ▶

Drug Facts (continued)

lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium starch glycolate

Questions or comments? Call 1-877-376-4271 (weekdays 9 AM to 5 PM)

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

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION



N 25000109281 8

Manufactured for: **Time-Cap Labs, Inc.**
7 Michael Avenue, Farmingdale, NY 11735
Manufactured by: **Markans Pharma Ltd.**
Plot No. L-82, L-83, Verna Indl. Estate, Verna, Goa-403722
Made in India Mfg. Lic. No. GO/DRUGS/515 R10624

LOT:
EXP:

Varnish Omit

NDC: 25000-092-03
Loratadine Tablets USP, 10 mg
30's count Carton

Varnish Omit
LOT:
EXP.:



Varnish Omit

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Drug Facts

Active ingredient Purpose (in each tablet)

Loratadine USP, 10mg.....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.

Drug Facts (continued)

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
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children under 6 years of age	ask a doctor
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consumers with liver or kidney disease	ask a doctor
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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 ingredients

colloidal silicon dioxide, lactose monohydrate, magnesium stearate,

Drug Facts (continued)

microcrystalline cellulose, sodium starch glycolate

Questions or comments?

Call 1-877-376-4271 (weekdays 9 AM to 5 PM)

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

NDC 25000-092-03
Compare to the active ingredient in Claritin® Tablets^{††}

Marksans
Original Prescription Strength
Non-Drowsy[®]

Loratadine Tablets USP, 10 mg

Antihistamine

Indoor & Outdoor Allergies

Relief of:

- ✓ Sneezing
- ✓ Itchy, watery eyes
- ✓ Runny nose
- ✓ Itchy throat or nose

30 TABLETS

*When taken as directed. See Drug Facts Panel.

24 HOURS



9283 Varnish/Print Omit Area

Varnish Omit

Manufactured for:
Time-Cap Labs, Inc.
7 Michael Avenue, Farmingdale,
NY 11735

Manufactured by:
Marksans Pharma Ltd.
Plot No. L-82, L-83, Verna Indl. Estate,
Verna, Goa-403722

Made in India
Mfg. Lic. No.: GO/DRUGS/515
R10624

NDC: 25000-092-03
Loratadine Tablets USP, 10 mg
30's count Label

Drug Facts (continued)

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 ingredients

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

Questions or comments?

Call 1-877-376-4271 (weekdays 9 AM to 5 PM)

Adhesive Area

Varnish Omit Area

LOT:
EXP:
PEEL HERE FOR MORE INFORMATION

Mfg. Lic. No. : GO/DRUGS/515 R10624

Made in India

Plot No. L-82, L-83, Verna Indl. Estate, Verna, Goa-403722

Manufactured by: **Marksans Pharma Ltd.**

7 Michael Avenue, Farmingdale, NY 11735

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

When using this product do not take

should determine if you need a different dose.

Ask a doctor before use if you have liver or kidney disease. Your doctor

allergic reaction to this product or any of its ingredients.

Warnings
Do not use if you have ever had an

■ itching of the nose or throat

■ sneezing

■ itchy, watery eyes

■ runny nose

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

Drug Facts
Active ingredient Purpose (in each tablet)
Loratadine USP, 10mg...Antihistamine

24 HOUR

*When taken as directed. See Drug Facts Panel.

30 TABLETS

Antihistamine
Indoor & Outdoor Allergies

Original Prescription Strength
Non-Drowsy*

Loratadine Tablets USP, 10 mg

M Marksans

NDC 25000-092-03

NDC: 25000-092-79
Loratadine Tablets USP, 10 mg
150's count Carton

Varnish Omit
LOT:
EXP:



READ AND KEEP CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Drug Facts

Active ingredient Purpose (in each tablet)

Loratadine USP, 10mg.....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.

Drug Facts (continued)

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 ingredients

colloidal silicon dioxide, lactose monohydrate, magnesium stearate,

Drug Facts (continued)

microcrystalline cellulose, sodium starch glycolate

Questions or comments?

Call 1-877-376-4271 (weekdays 9 AM to 5 PM)

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

NDC 25000-092-79
Compare to the active ingredient in Claritin® Tablets†



Original Prescription Strength

Non-Drowsy*

Loratadine Tablets USP, 10 mg

Antihistamine

Indoor & Outdoor Allergies

Relief of:

- ✓ Sneezing
- ✓ Itchy, watery eyes
- ✓ Runny nose
- ✓ Itchy throat or nose

150 TABLETS

*When taken as directed. See Drug Facts Panel.

Varnish Omit

Varnish Omit

9283 Varnish/Print Omit Area

NDC: 25000-092-79
Loratadine Tablets USP, 10 mg
150's count Label

M Marksans NDC 25000-092-79

Original Prescription Strength
Non-Drowsy*

Loratadine Tablets USP, 10 mg

Antihistamine
Indoor & Outdoor Allergies

Relief of:

- ✓ Sneezing ✓ Itchy, watery eyes
- ✓ Runny nose ✓ Itchy throat or nose

150 TABLETS *When taken as directed. See Drug Facts Panel.

24
HOUR

Drug Facts

Active ingredient Purpose (in each tablet)
Loratadine USP, 10mg... 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 ▶

Manufactured for: Time-Cap Labs, Inc.
7 Michael Avenue, Farmingdale, NY 11735
Manufactured by: Marksans Pharma Ltd.
Plot No. L-82, L-83, Verna Indl. Estate,
Verna, Goa-403722

Made in India
Mfg. Lic. No. : GO/DRUGS/515 R10624

Varnish Omit Area

LOT:
EXP:

SEE HERE FOR MORE INFORMATION

NDC: 25000-092-80
Loratadine Tablets USP, 10 mg
365's count Label

Drug Facts (continued)
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 ingredients colloidal silicon dioxide, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium starch glycolate

Questions or comments?
Call 1-877-376-4271 (weekdays 9 AM to 5 PM)

Adhesive Area

Drug Facts (continued)

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

Questions or comments? Call 1-877-376-4271 (weekdays 9 AM to 5 PM)

Adhesive Area

Marksans NDC 25000-092-80
Compare to the active ingredient in Claritin® Tablets†

Original Prescription Strength
Non-Drowsy*

Loratadine Tablets USP, 10 mg

Antihistamine
Indoor & Outdoor Allergies
Relief of:

- ✓ Sneezing ✓ Itchy, watery eyes
- ✓ Runny nose ✓ Itchy throat or nose

365 TABLETS
*When taken as directed. See Drug Facts Panel.

24 HOUR

Drug Facts

Active ingredient (in each tablet)
Loratadine USP, 10mg.....Antihistamine

Purpose
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

Uses

Warnings
Do not use if you have ever had an allergic reaction to this product or any of its ingredients.

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Manufactured for: **Time-Cap Labs, Inc.**
7 Michael Avenue, Farmingdale, NY 11735
Manufactured by: **Marksans Pharma Ltd.**
Plot No. L-82, L-83, Verma Indl. Estate, Verma, Goa-403722

Made in India
Mfg. Lic. No. : GO/DRUGS/515
R10624

LOT: _____ EXP: _____

Varnish Omit Area

PEEL HERE FOR MORE INFORMATION

LORATADINE 10MG			
loratadine 10mg tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:25000-092
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	

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:25000-092-03	1 in 1 CARTON	11/21/2024	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:25000-092-79	1 in 1 CARTON	11/21/2024	
2		150 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:25000-092-81	2 in 1 CARTON	11/21/2024	
3		7 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:25000-092-80	365 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA219223	11/21/2024	

Labeler - MARKSANS PHARMA LIMITED (925822975)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	MANUFACTURE(25000-092)