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 20º to 25º C (68º to 77º 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,

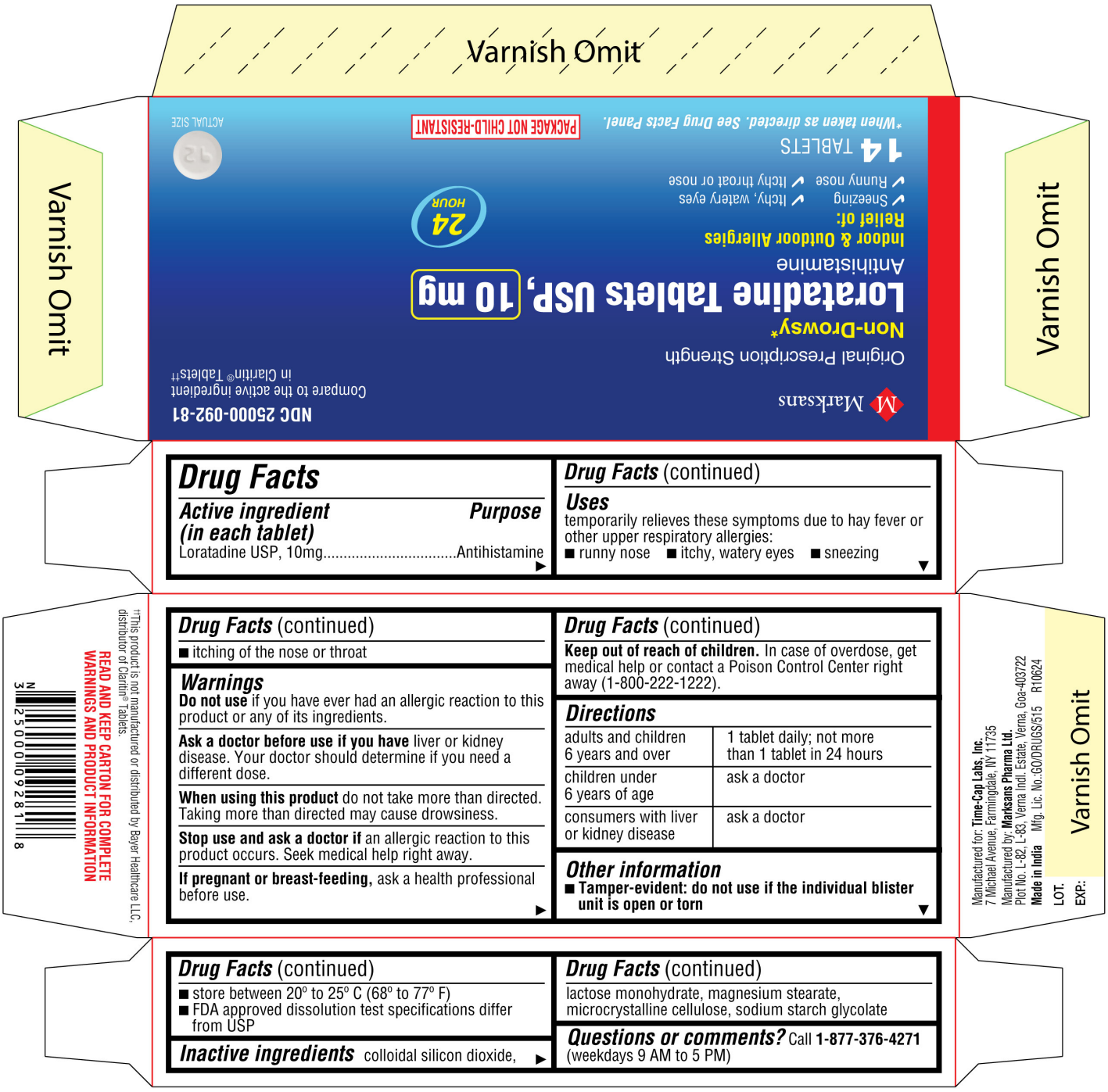
Farmingdale,
NY 11735

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

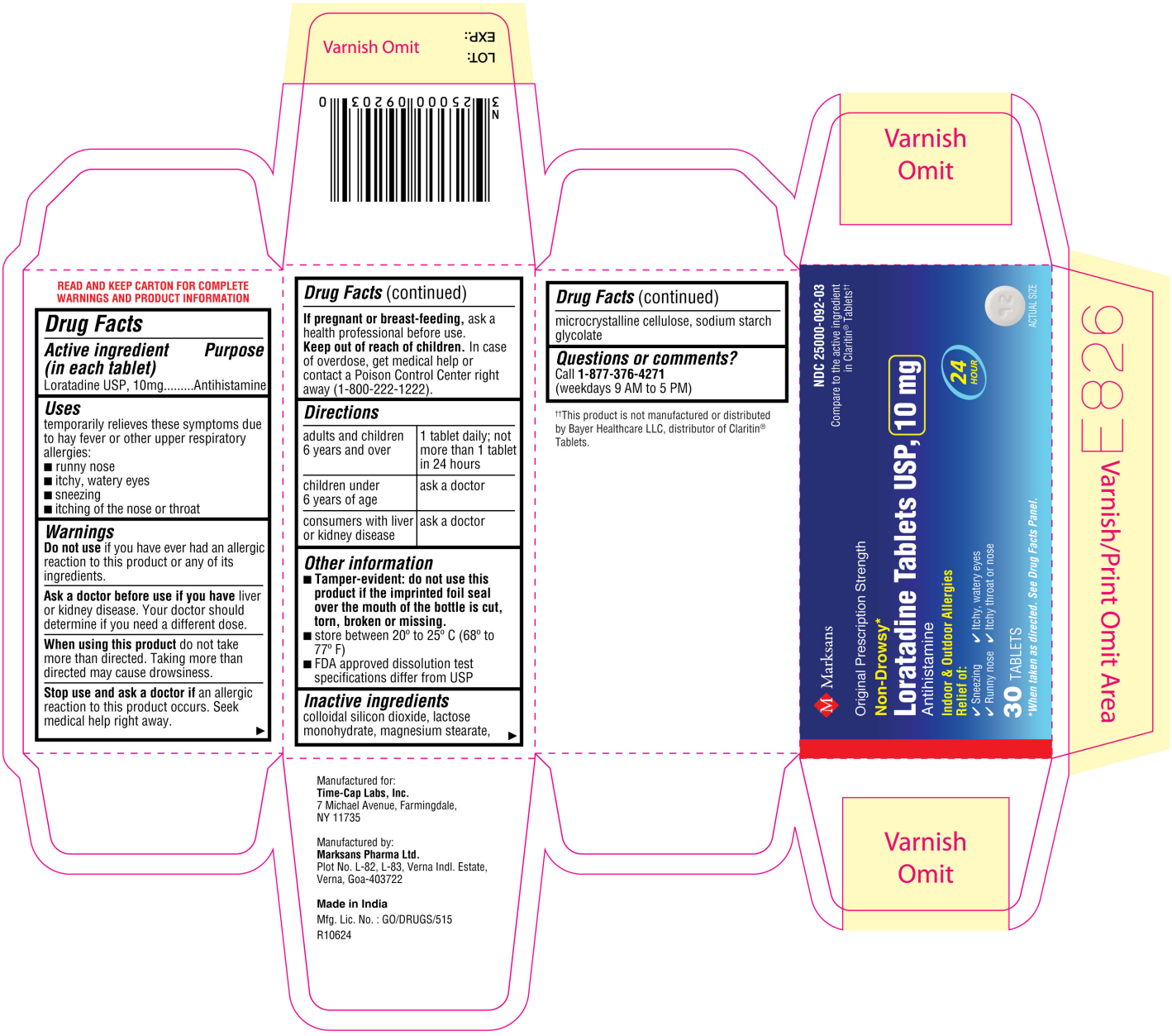
Made in India

PRINCIPAL DISPLAY PANEL

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

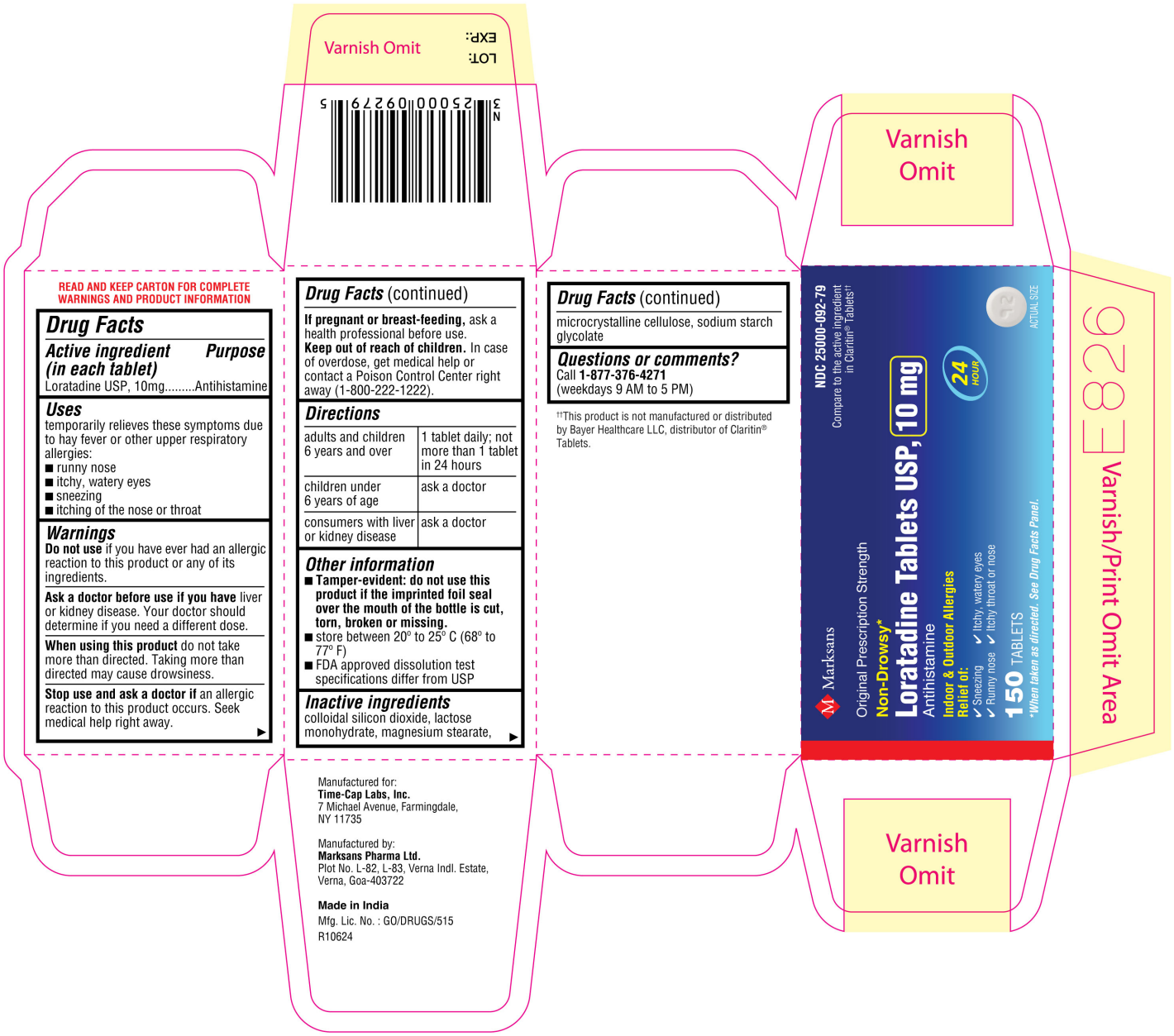


NDC: 25000-092-03
Loratadine Tablets USP, 10 mg
30's count Carton



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

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



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

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

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

NDC 25000-092-80
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

24 HOUR

365 TABLETS

*When taken as directed.
See Drug Facts Panel.

ACTUAL SIZE

Drug Facts

Active ingredient (in each tablet)	Purpose
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. ▲

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

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

LOT:
EXP:

PEEL HERE FOR MORE INFORMATION

Varnish Omit Area

LORATADINE 10MG

loratadine 10mg tablet

Product Information	
Product Type	HUMAN OTC DRUG
Route of Administration	ORAL

Item Code (Source)	NDC:25000-092

Active Ingredient/Active Moiety	
Ingredient Name	**Basis of Strength**
LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN)	LORATADINE

Strength
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)

Revised: 11/2024 MARKSANS PHARMA LIMITED