FAMOTIDINE 10 MG - famotidine 10 mg tablet, coated
FAMOTIDINE 20 MG - famotidine 20 mg tablet, coated
MARKSANS PHARMA LIMITED

Famotidine Tablets USP, 10 mg and 20 mg

Active ingredient (in each tablet)

For 10 mg:

Famotidine USP 10 mg

For 20 mg:

Famotidine USP 20 mg

Purpose

Acid Reducer

Uses

- relieves heartburn associated with acid indigestion and sour stomach
- prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain food and beverages

Warnings

Allergy alert: Do not use if you are allergic to famotidine or other acid reducers

Do not use

• if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
• with other acid reducers

Ask a doctor before use if you have

• had heartburn over 3 months. This may be a sign of a more serious condition.
• heartburn with **lightheadedness, sweating, or dizziness**
• chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
• frequent **chest pain**
• frequent wheezing, particularly with heartburn
• unexplained weight loss

• nausea or vomiting
• stomach pain
• kidney disease

Ask a doctor or pharmacist before use if you are

taking a prescription drug. Acid reducers may interact with certain prescription drugs.

Stop use and ask a doctor if

• your heartburn continues or worsens
• you need to take this product for more than 14 days

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

For 10mg:

• adults and children 12 years and over:
o to **relieve** symptoms, swallow 1 tablet with a glass of water. Do not chew.
o to **prevent** symptoms, swallow 1 tablet with a glass of water at any time from **15 to 60 minutes before** eating food or drinking beverages that cause heartburn
o do not use more than 2 tablets in 24 hours
• children under 12 years: ask a doctor

For 20 mg:

• adults and children 12 years and over:
o to **relieve** symptoms, swallow 1 tablet with a glass of water. Do not chew.
o to **prevent** symptoms, swallow 1 tablet with a glass of water at any time from **10 to 60 minutes before** eating food or drinking beverages that cause heartburn
o do not use more than 2 tablets in 24 hours
• children under 12 years: ask a doctor

Other information

• read the directions and warnings before use
• keep the carton. It contains important information.
• store at 20°-25°C (68°-77°F)

• protect from moisture
• FDA approved dissolution test specifications differ from USP

Inactive ingredients

For 10 mg:

carnauba wax, colloidal silicon dioxide, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, pregelatinized starch, red iron oxide, talc, titanium dioxide

For 20 mg:

carnauba wax, colloidal silicon dioxide, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, pregelatinized starch, talc, titanium dioxide

Questions or comments?

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

- **JUST ONE TABLET** prevents and relieves heartburn due to acid indigestion brought on by eating and drinking certain foods and beverages.

Tips for Managing Heartburn
• Do not lie flat or bend over after eating
• Do not wear tight-fitting clothing around the stomach
• Do not eat before bedtime
• Raise the head of your bed
• Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol, and certain fruits and vegetables
• Eat slowly and avoid big meals
• If overweight, lose weight
• Quit smoking

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

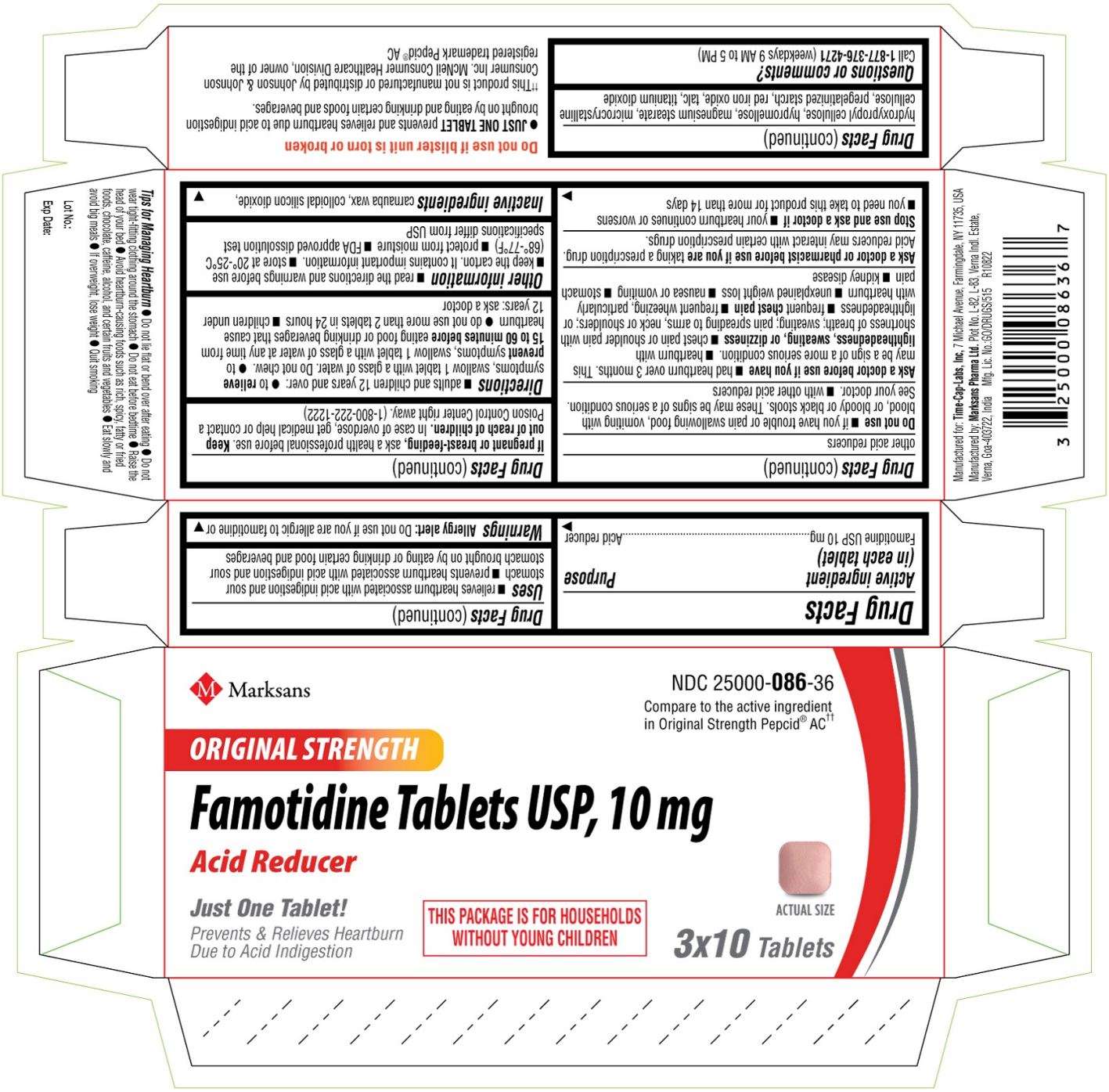
PRINCIPAL DISPLAY PANEL

Famotidine Tablets USP, 10 mg

NDC: 25000-086-36

Famotidine Tablets USP 10 mg

30's (3 x 10's blister) count Carton Label



NDC: 25000-086-03

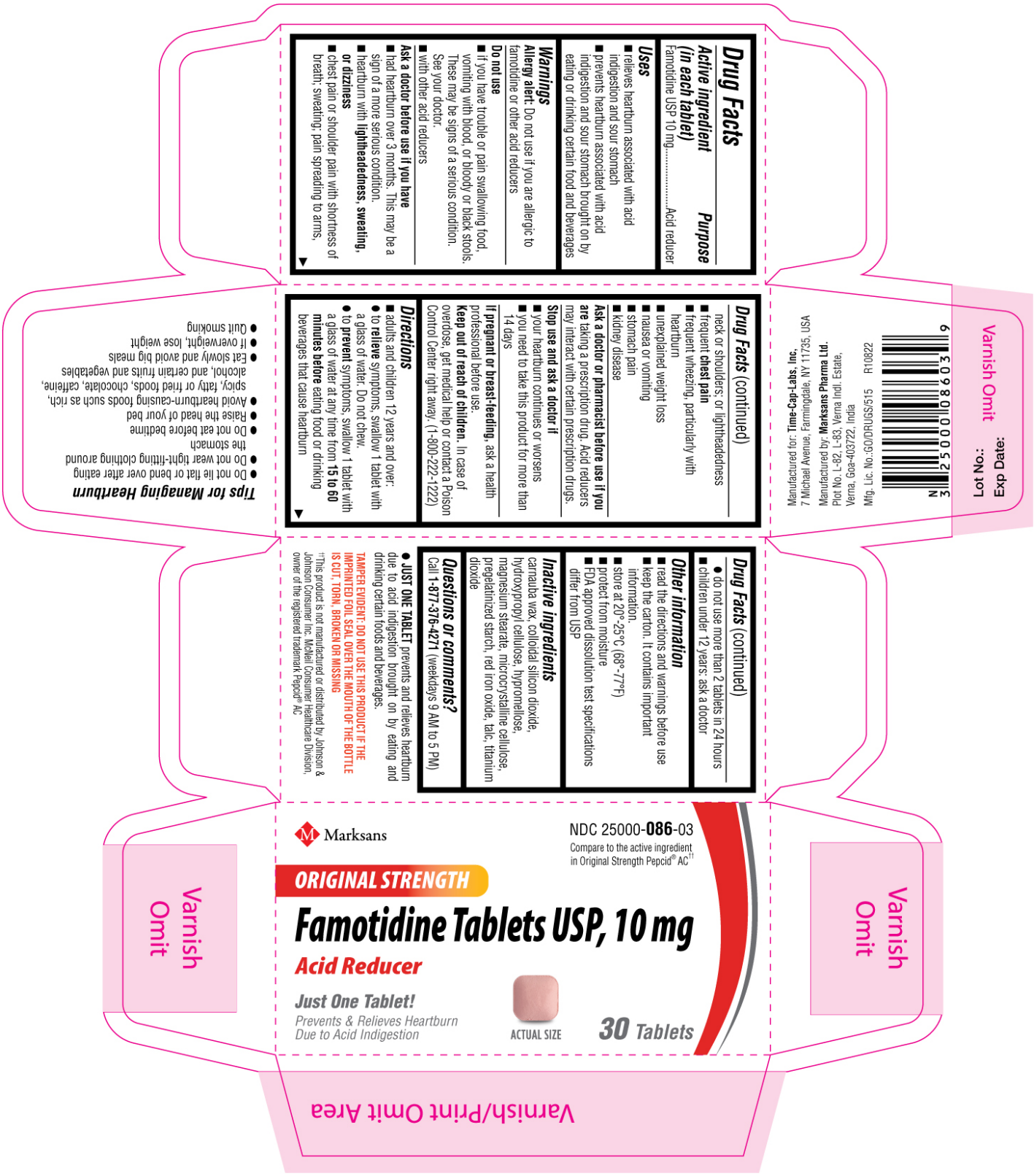
Famotidine Tablets USP 10 mg

30's count Bottle Label

NDC: 25000-086-03

Famotidine Tablets USP 10 mg

30's count Carton Label



NDC: 25000-086-08

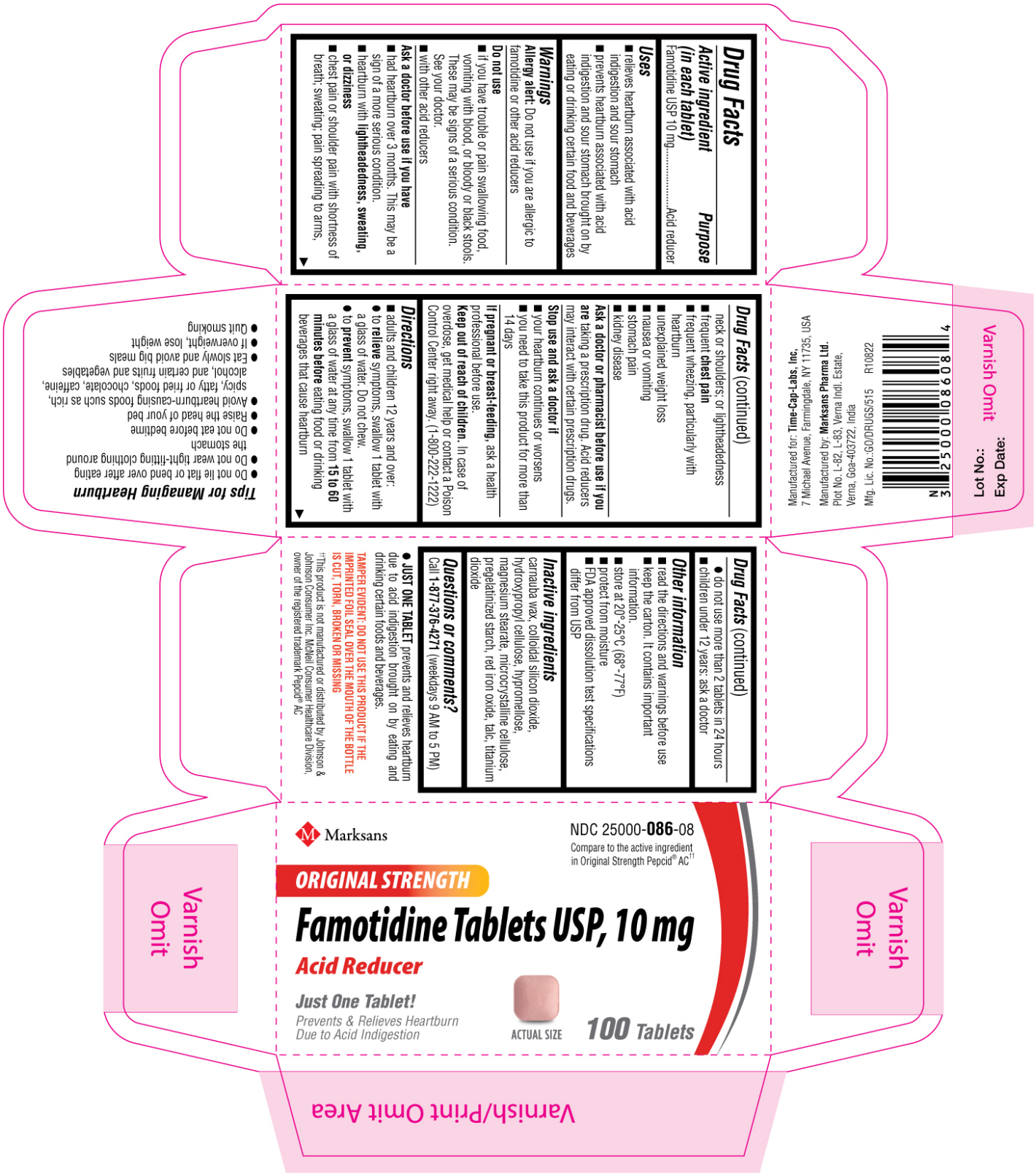
Famotidine Tablets USP 10 mg

100's count Bottle Label

NDC: 25000-086-08

Famotidine Tablets USP 10 mg

100's count Carton Label

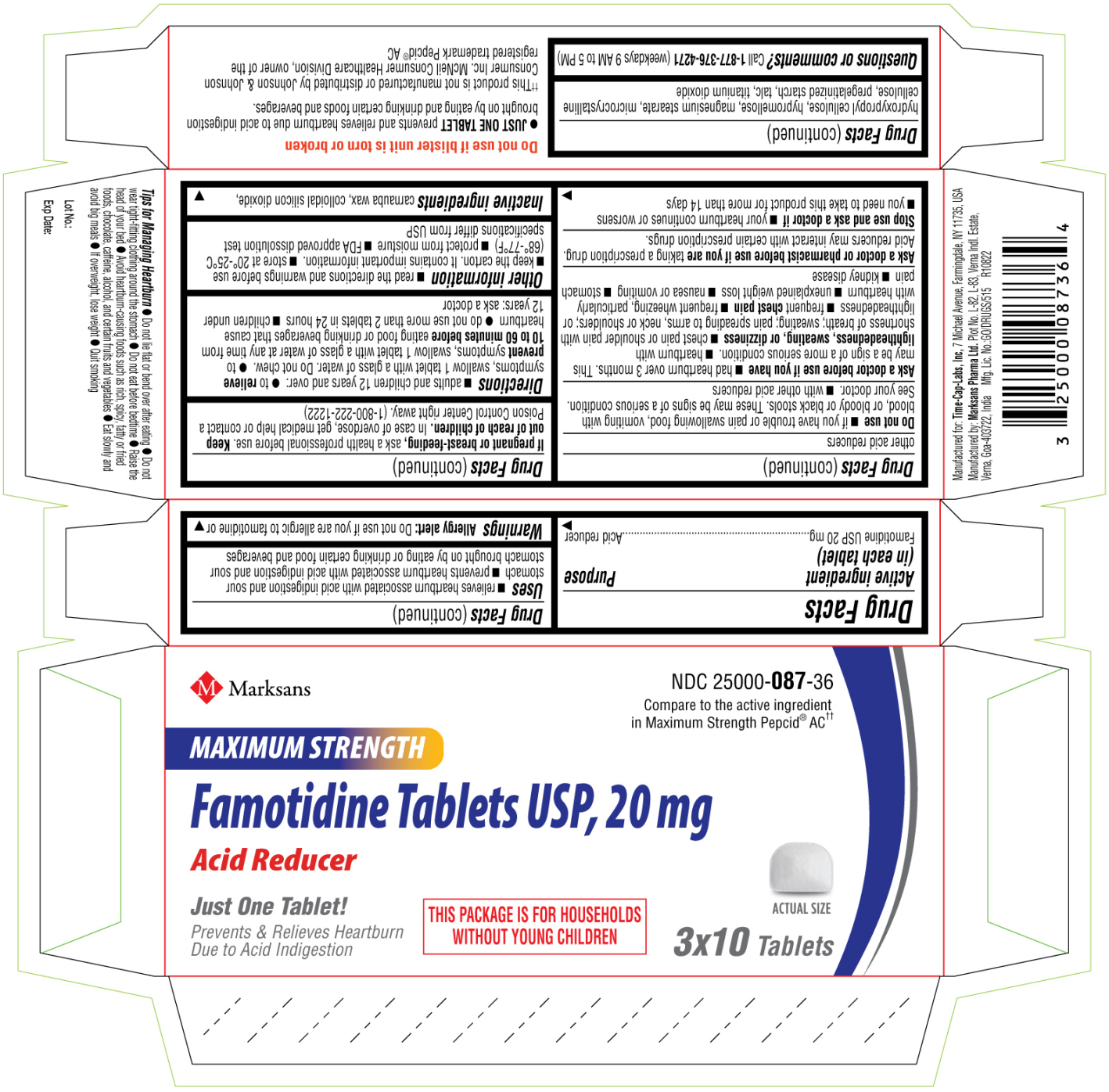


Famotidine Tablets USP, 20 mg

NDC: 25000-087-36

Famotidine Tablets USP 20 mg

30's (3 x 10's blister) count Carton Label



NDC: 25000-087-03

Famotidine Tablets USP 20 mg

30's count Bottle Label

NDC: 25000-087-03

Famotidine Tablets USP 20 mg

30's count Carton Label

NDC: 25000-087-08

Famotidine Tablets USP 20 mg

100's count Bottle Label

NDC: 25000-087-08

Famotidine Tablets USP 20 mg

100's count Carton Label

NDC: 25000-087-82

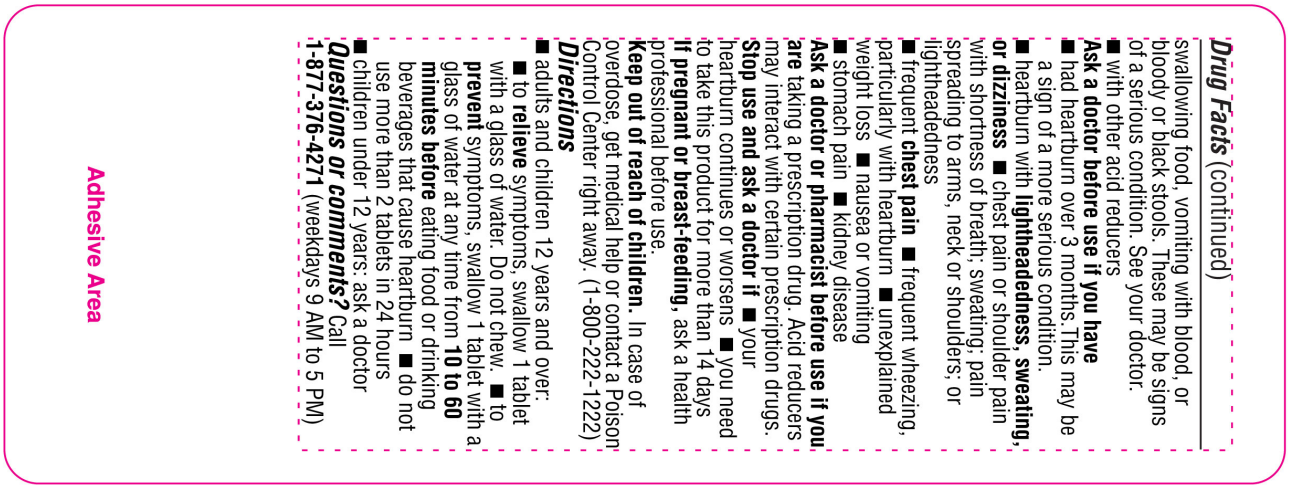
Famotidine Tablets USP 20 mg

200's count Carton Label

NDC: 25000-087-82

Famotidine Tablets USP 20 mg

200's count Bottle Label



Inside

FAMOTIDINE 10 MG

famotidine 10 mg tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:25000-086
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Famotidine (UNII: 5QZO15J2Z8) (Famotidine - UNII:5QZO15J2Z8)	Famotidine	10 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
STARCH, CORN (UNII: O8232NY3SJ)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	PINK	**Score**	no score
Shape	SQUARE	**Size**	7mm
Flavor		**Imprint Code**	86
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:25000-086-36	3 in 1 CARTON	03/10/2023	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:25000-086-03	1 in 1 CARTON	03/10/2023	
2		30 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:25000-086-08	1 in 1 CARTON	03/10/2023	
3		100 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:25000-086-07	1 in 1 CARTON	04/24/2024	
4		90 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA217543	03/10/2023	

FAMOTIDINE 20 MG

famotidine 20 mg tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:25000-087
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Famotidine (UNII: 5QZO15J2Z8) (Famotidine - UNII:5QZO15J2Z8)	Famotidine	20 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE	**Score**	no score
Shape	SEMI-CIRCLE (D-shaped)	**Size**	9mm
Flavor		**Imprint Code**	87
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:25000-087-36	3 in 1 CARTON	03/10/2023	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:25000-087-03	1 in 1 CARTON	03/10/2023	
2		30 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:25000-087-08	1 in 1 CARTON	03/10/2023	
3		100 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:25000-087-05	1 in 1 CARTON	04/24/2024	
4		50 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:25000-087-82	1 in 1 CARTON	02/15/2024	
5		200 in 1 BOTTLE; Type 0: Not a Combination		

3		Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA217543	03/10/2023	

Labeler - MARKSANS PHARMA LIMITED (925822975)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	MANUFACTURE(25000-086, 25000-087)

Revised: 4/2024 MARKSANS PHARMA LIMITED