

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
- Meets USP dissolution test 2

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

30's count Bottle Label

Drug Facts (continued)

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

- adults and children 12 years and over, ■ to **relieve** symptoms, swallow 1 tablet with a glass of water. Do not chew.
- 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
- do not use more than 2 tablets in 24 hours
- children under 12 years: ask a doctor

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

Adhesive Area

 Marksans ORIGINAL STRENGTH <h1>Famotidine Tablets USP, 10 mg</h1> <i>Acid Reducer</i> Just One Tablet! Prevents & Relieves Heartburn Due to Acid Indigestion	 ACTUAL SIZE	<p>NDC 25000-086-03</p> <div style="border: 1px solid black; padding: 5px;"> <p>TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING</p> <p>KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION</p> </div> <h2>Drug Facts</h2> <p>Active ingredient (in each tablet) Famotidine 10 mg.....Acid reducer</p> <p>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</p> <p>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 ▼</p> <p>Drug Facts (continued under label)</p> <p>Manufactured for: Time-Cap Labs, Inc. 7 Michael Avenue, Farmingdale, NY 11735, USA</p> <p>Manufactured by: Marksans Pharma Ltd. Plot No. L-82 I-83, Verna Indl. Estate, Verna, Goa-403722, India</p> <p>Mfg. Lic. No.-GO0DRUGS15 R20924</p>	<p>Varnish Omit Area</p> <p>LOT: _____ EXP: _____</p> <p>FREE HERE →</p>
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30's count Carton Label

Varnish Omit

EXP :
LOT :



R20924

Mfg. Lic. No. G009090515

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

Manufactured by: **Marksans Pharma Ltd.**

7 Michael Avenue, Farmingdale, NY 11735, USA

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

Drug Facts

Active ingredient
(in each tablet)
Famotidine USP 10 mg..... 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.

Drug Facts (continued)

- 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

- adults and children 12 years and over:
 - to **relieve** symptoms, swallow 1 tablet with a glass of water. Do not chew.
 - 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

Tips for Managing Heartburn

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

Drug Facts (continued)

- 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
- Meets USP dissolution test 2

Inactive ingredients

cambeba wax, colloidal silicon dioxide, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, pregelatinized starch, red iron oxide, 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.

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING

†This product is not manufactured or distributed by Johnson & Johnson Consumer Inc. McKel Consumer Healthcare Division, owner of the registered trademark Peppid® AC



NDC 25000-086-03

Compare to the active ingredient in Original Strength Peppid® AC†

ORIGINAL STRENGTH

Famotidine Tablets USP, 10 mg

Acid Reducer

Just One Tablet!

Prevents & Relieves Heartburn
Due to Acid Indigestion



ACTUAL SIZE

30 Tablets

Varnish/Print Omit Area

Varnish
Omit

Varnish
Omit

NDC: 25000-086-08

Famotidine Tablets USP 10 mg

100's count Bottle Label

30's count Bottle Label

30's count Bottle Label


Marksans

NDC 25000-087-03

MAXIMUM STRENGTH

Famotidine Tablets USP, 20 mg

Acid Reducer

Just One Tablet!
Prevents & Relieves Heartburn
Due to Acid Indigestion

30 Tablets



ACTUAL SIZE

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING

KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION

Drug Facts

Active ingredient
(in each tablet)
Famotidine 20 mg.....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

Drug Facts (continued under label)

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

Mfg. Lic. No.: G00DRUGS/15 R20924

LOT:
EXP.:

Varnish Omit Area

Drug Facts (continued)

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
■ adults and children 12 years and over:
■ to relieve symptoms, swallow 1 tablet with a glass of water. Do not chew.
■ 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
■ do not use more than 2 tablets in 24 hours
■ children under 12 years: ask a doctor

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

Adhesive Area

NDC: 25000-087-03

Famotidine Tablets USP 20 mg

30's count Carton Label

Varnish Omit

EXP
: LOT1



Mfg. Lic. No. 60/DPRUGS/515 R20924

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

Manufactured by: **Marksans Pharma Ltd.**

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

Drug Facts

Active ingredient **Purpose**
(in each tablet) Acid reducer
Famotidine USP 20 mg.....

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,

Drug Facts (continued)

- 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

- adults and children 12 years and over:
 - to **relieve symptoms**, swallow 1 tablet with a glass of water. Do not chew.
 - 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

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 and fried foods, chocolate, caffeine, alcohol, and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

Drug Facts (continued)

- 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
- Meets USP dissolution test 2

Inactive ingredients

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.

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING

*This product is not manufactured or distributed by Johnson & Johnson Consumer Inc. McNeil Consumer Healthcare Division, owner of the registered trademark Peppid® AC



NDC 25000-087-03
Compare to the active ingredient
in Maximum Strength Peppid® AC†

MAXIMUM STRENGTH

Famotidine Tablets USP, 20 mg

Acid Reducer

Just One Tablet!

Prevents & Relieves Heartburn
Due to Acid Indigestion



30 Tablets

Varnish/Print Omit Area

Varnish
Omit

Varnish
Omit

NDC: 25000-087-08

Famotidine Tablets USP 20 mg

100's count Bottle Label

Varnish Omit

EXP
: LOT1



Mfg. Lic. No. 60/DPRUGS/515 R20924

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

Manufactured by: **Marksans Pharma Ltd.**

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

Drug Facts

Active ingredient **Purpose**
(in each tablet) Acid reducer
Famotidine USP 20 mg.....

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,

Drug Facts (continued)

- 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

- adults and children 12 years and over:
 - to **relieve symptoms**, swallow 1 tablet with a glass of water. Do not chew.
 - 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

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 and fried foods, chocolate, caffeine, alcohol, and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

Drug Facts (continued)

- 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
- Meets USP dissolution test 2

Inactive ingredients

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.

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS OUT, TORN, BROKEN OR MISSING

*This product is not manufactured or distributed by Johnson & Johnson Consumer Inc. McNeil Consumer Healthcare Division, owner of the registered trademark Pepcid® AC



NDC 25000-087-08
Compare to the active ingredient
in Maximum Strength Pepcid® AC†

MAXIMUM STRENGTH

Famotidine Tablets USP, 20 mg

Acid Reducer

Just One Tablet!

Prevents & Relieves Heartburn
Due to Acid Indigestion



ACTUAL SIZE

100 Tablets

Varnish/Print Omit Area

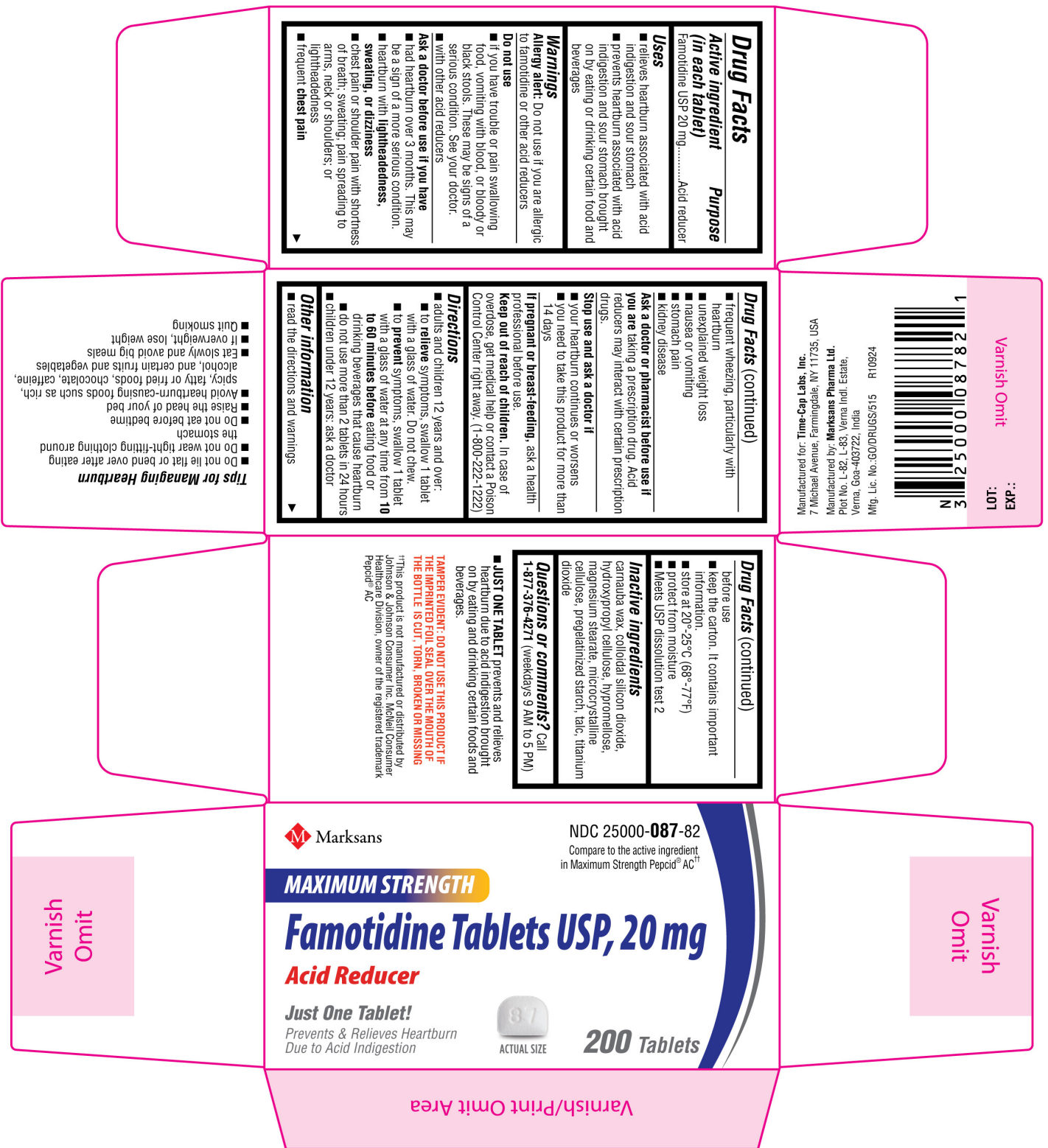
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NDC: 25000-087-82

Famotidine Tablets USP 20 mg

200's count Carton Label



Drug Facts (continued)

Other information

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Drug Facts (continued)

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

- adults and children 12 years and over: ■ to relieve symptoms, swallow 1 tablet with a glass of water. Do not chew. ■ 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 ■ do not use more than 2 tablets in 24 hours
- children under 12 years: ask a doctor

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

Adhesive Area

NDC 25000-087-82

M

Marksans

MAXIMUM STRENGTH

Famotidine Tablets USP, 20 mg

Acid Reducer

Just One Tablet!

Prevents & Relieves Heartburn

Due to Acid Indigestion

200 Tablets

ACTUAL SIZE

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING

KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION

Drug Facts

Active ingredient (in each tablet)

Famotidine USP 20 mg.....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

Drug Facts (continued under label)

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
Mfg. Lic. No.:GO/DRUGS/515 R10924

LOT:

EXP.:

PEEL HERE

Varnish Omit Area

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: 70097M6I3O)	
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: 70097M6I3O)					
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 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: 9/2024

MARKSANS PHARMA LIMITED