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

Ask a doctor before use if you have = had heartburn over 3 months. This may be a sign of a more serious condition. sweating, or dizziness = chest pain or shoulder pain with shortness of breath; sweating, 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 heed 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. Do not chew. • to 0 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 <i>Questions or comments?</i> Call 1-877-376-4271 (weekdays 9 AM to 5 PM)	Drug Facts (continued) bloody or black stools. These may be signs of a serious condition. See your
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NDC: 25000-086-08 Famotidine Tablets USP 10 mg 100's count Carton Label



Famotidine Tablets USP, 20 mg

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

Adhesive 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 a sign of a more serious condition. had heartburn with lightheadedness, sweating; pain spreading to arms, neck or shoulders; or lightheadedness of breath; sweating, particularly with heartburn unexplained weight loss ■ nausea or yourniting ■ 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 drug. 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 certain professional before use, 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 hearthurn ● do not use more from 12 years: ask a doctor if 2 years: ask a doctor for S = adults and children 12 years: ask a doctor for tablets in 24 hours ■ children to than 2 tablets in 24 hours ■ children to than 2 tablets in 24 hours ■ children to than 2 tablets in 24 hours ■ children to than 2 tablets in 24 hours ■ children to to 5 PM) 	
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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, coate	ed				
Product Information					
Product Type	HUMAN OTC DRUG	ltem Code (Source)	NDC:25	000-086
Route of Administration	ORAL				
Active Ingredient/Active	Moiety				
Ingred	lient Name		Basis of Stre	ength	Strength
Famotidine (UNII: 5QZ015J2Z8) (F	amotidine - UNII:5QZO15J2	2Z8)	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: 08232NY3SJ)	
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

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

FAMOTIDINE 20 MG

famotidine 20 mg tablet, coated

Product Information

Product Type		HUMAN OTC DRUG	tem Code (So	ource)	NDC:25	000-087
Route of Admin	istration	ORAL				
Active Ingred	ient/Active	Moiety				
	Ingred	dient Name		Basis of Str	ength	Strength
Famotidine (UNII:	5QZO15J2Z8) (Famotidine - UNII:5QZ015J2Z	8) Fa	amotidine		20 mg
Inactive Ingre	edients					
		Ingredient Name				Strength
CARNAUBA WAX (
SILICON DIOXIDE						
			мбОН)			
· ·		(UNII: 3NXW29V3WO)				
MAGNESIUM STEA		E 102 (UNII: PNR0YF693Y)				
STARCH, CORN (U						
TALC (UNII: 7SEV7)		<i>J</i> /				
		(2IP)				
Product Char	acteristics					
Color	WHITE		Score		no	score
Shape	SEMI-CIRCLE	(D-shaped)	Size		9m	im
	SEMI-CIRCLE	(D-shaped)	Size Imprint	Code	9m 87	im
Shape Flavor Contains	SEMI-CIRCLE	(D-shaped)		Code		im
Flavor	SEMI-CIRCLE	(D-shaped)		Code		im
Flavor Contains	S EMI-CIRCLE	(D-shaped)		Code		im
Flavor Contains	SEMI-CIRCLE	(D-shaped)	Imprint		87	
Flavor Contains Packaging		(D-shaped) ckage Description	Imprint	Code eting Start Date	87 Mark	eting End Date
Flavor Contains Packaging # Item Code			Imprint	eting Start Date	87 Mark	eting End
Flavor Contains Packaging # Item Code 1 NDC:25000- 087-36	Pa 3 in 1 CARTON		Imprint of Mark 03/10/20	eting Start Date	87 Mark	eting End
Flavor Contains Packaging # Item Code	Pa 3 in 1 CARTON 10 in 1 BLISTE	ckage Description	Imprint of Mark 03/10/20	eting Start Date	87 Mark	eting End
Flavor Contains Packaging # Item Code 1 NDC:25000- 087-36 1 NDC:25000- 087-03	Pa 3 in 1 CARTON 10 in 1 BLISTEI Product 1 in 1 CARTON	ckage Description	Mark 03/10/20	eting Start Date	87 Mark	eting End
Flavor Contains Packaging # Item Code 1 NDC:25000- 087-36 1	Pa 3 in 1 CARTON 10 in 1 BLISTE Product 1 in 1 CARTON 30 in 1 BOTTLE	ckage Description R PACK; Type 0: Not a Combi	Mark 03/10/20	eting Start Date	87 Mark	eting End
Flavor Contains Packaging # Item Code 1 NDC:25000- 087-36 1 NDC:25000- 087-03 2 NDC:25000- 087-03 2 NDC:25000- 087-03	Pa 3 in 1 CARTON 10 in 1 BLISTE Product 1 in 1 CARTON 30 in 1 BOTTLE Product 1 in 1 CARTON	ckage Description R PACK; Type 0: Not a Combi	Mark 03/10/20 03/10/20	eting Start Date	87 Mark	eting End
Flavor Contains Packaging # Item Code 1 NDC:25000- 087-36 2 NDC:25000- 087-03 2 NDC:25000- 087-03 3 NDC:25000- 087-08	Pa 3 in 1 CARTON 10 in 1 BLISTE Product 1 in 1 CARTON 30 in 1 BOTTLE Product 1 in 1 CARTON 100 in 1 BOTTLE	ckage Description R PACK; Type 0: Not a Combi E; Type 0: Not a Combination	Mark 03/10/20 03/10/20	eting Start Date	87 Mark	eting End
Flavor Contains Packaging # Item Code 1 NDC:25000- 2 NDC:25000- 3 NDC:25000- 3 NDC:25000- 3 NDC:25000- 3 NDC:25000- 3 NDC:25000-	Pa 3 in 1 CARTON 10 in 1 BLISTED Product 1 in 1 CARTON 30 in 1 BOTTLE Product 1 in 1 CARTON 100 in 1 BOTTLE Product 1 in 1 CARTON 101 in 1 CARTON	ckage Description R PACK; Type 0: Not a Combi E; Type 0: Not a Combination	Mark 03/10/20 nation 03/10/20	eting Start Date	87 Mark	eting End
Flavor Contains Packaging # Item Code 1 NDC:25000- 2 NDC:25000- 3 NDC:25000- 4 NDC:25000-	Pa 3 in 1 CARTON 10 in 1 BLISTER Product 1 in 1 CARTON 30 in 1 BOTTLE Product 1 in 1 CARTON 100 in 1 BOTTLE 100 in 1 BOTTLE 1 in 1 CARTON 50 in 1 BOTTLE	ckage Description R PACK; Type 0: Not a Combi E; Type 0: Not a Combination LE; Type 0: Not a Combinatio	Mark 03/10/20 nation 03/10/20	eting Start Date 023 023 023	87 Mark	eting End

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