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

Famotidine Tablets USP, 20 mg - Cool Mint Flavor

ACTIVE INGREDIENT(S)

Active ingredient (in each tablet)

Famotidine USP 20 mg

PURPOSE

Purpose

Acid reducer

USE(S)

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

Warnings

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

DO NOT USE

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

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

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 DOCTOR IF

Stop use and ask a doctor if

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

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 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

OTHER INFORMATION

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

Inactive ingredients carnauba wax, colloidal silicon dioxide, flavor, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, pregelatinized

QUESTIONS OR COMMENTS

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

NDC: 25000-124-94

Famotidine Tablets USP 20 mg- Cool mint flavor 25's (5 x 5's blister) count Carton Label

Manufactured for:

Time-Cap Labs, Inc.

Timeshal Evenue, Farmingdale, NY 11735, USA
Marksans Pharma Ltd.

Marksans Pharma Ltd.

Mg. Lic. No.:Go/DRUGS/515

Mg. Lic. No.:Go/DRUGS/515



NDC: 25000-124-84

Adhesive Area

Drug Facts (continued)

Drug Facts (continued)

Warnings

Directions

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

do not use more than 2 tablets beverages that cause heartburn before eating food or drinking time from 10 to 60 minutes

read the directions and warnings

Other information

■ children under 12 years: ask a docto

Allergy alert: Do not use if you are allergic to famotidine or other acid ■ if you have trouble or pain Do not use educers blood, or bloody or black stools swallowing food, vomiting with

with other acid reducers condition. See your doctor. These may be signs of a serious

condition. may be a sign of a more serious

Ask a doctor before use if you have ■ had heartburn over 3 months. This

trequent wheezing, particularly with trequent chest pain shoulders; or lightheadedness spreading to arms, neck or

chest pain or shoulder pain with sweating, or dizziness heartburn with lightheadedness,

shortness of breath; sweating; pain

kidney disease unexplained weight loss **use if you are** taking a prescription ASK a doctor or pharmacist before nausea or vomiting stomach pain heartburn

hypromellose, magnesium stearate, microcrystalline cellulose, pregelatinized

starch, sodium saccharin, talc, titanium

carnauba wax, colloidal silicon dioxide

nactive ingredients

Meets USP dissolution test 2 protect from moisture

flavor, hydroxypropyl cellulose,

important information.
■ store at 20°-25°C (68°-77°F)

keep the carton. It contains

before use

Questions or comments? Call 1-877-376-4271

weekdays 9 AM to 5 PM

or contact a Poison Control Center in case of overdose, get medical help (eep out of reach of children. lealth professional before use. pregnant or breast-feeding, ask a

ight away. (1-800-222-1222)

you need to take this product for

more than 14 days

your heartburn continues or worsens

Stop use and ask a doctor if

drug. Acid reducers may interact with

certain prescription drugs.

NDC 25000-**124**-84 Varnish Omit Area Acid reducer prevents heartburn associated with ■ relieves heartburn associated with acid indigestion and sour stomach acid indigestion and sour stomach brought on by eating or drinking certain food and beverages **BROKEN OR** Marksans Pharma Ltd. Plot No. L-82, L-83, Verna Indl. Estate, Verna, Goa-403722, India USE THIS I Famotidine Tablets USP, 20 mg **Drug Facts** (continued 7 Michael Avenue, Farmingdale Active inaredient -amotidine USP 20 mg. Mfg. Lic. No.:GO/DRUGS/515 HE IMPRINTED FOIL SEAL HE BOTTLE IS CUT, TORN, 'in each tablet Time-Cap Labs, Inc. Manufactured for Manufactured by: NY 11735, USA EXP.: L01: Uses **ACTUAL SIZE** R00924 **25** Tablets

NDC: 25000-124-84

Marksans

Acid Reducer

Just One Tablet!

Due to Acid Indigestion

Cool Mint

Elayor

Prevents & Relieves Heartburn

MAXIMUM STRENGTH

Famotidine Tablets USP 20 mg- Cool mint flavor

25's count Carton Label



NDC: 25000-124-68

Famotidine Tablets USP 20 mg- Cool mint flavor

300's count Bottle Label

Drug Facts (continued)

- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- unexplained weight loss
- frequent chest pain frequent wheezing, **Ask a doctor or pharmacist before use if you are** taking a prescription drug Acid reducers may interact with certain prescription drugs. stomach pain ■ kidney disease nausea or vomiting particularly with heartburn

Stop use and ask a doctor it

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
contact a Poison Control Center right away. (1-800-222-1222) 9

adults and children 12 years and over:

■ to relieve symptoms, swallow 1 tablet with a glass of water. Do not chew

■ had heartburn over 3 months. This may be a sign of a more serious condition.
■ heartburn with lightheadedness, sweating, or dizziness

Ask a doctor before use if you have

■ with other acid reducers

Do not use

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

Drug Facts

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

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

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.

do not use more than 2 tablets in 24 hours 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 nearrourn

Jther Information read the directions and warnings before use store at 20°-25°C (68°-77°F)

protect from moisture Meets USP dissolution test 2

children under 12 years: ask a doctor

carnauba wax, colloidal silicon dioxide, flavor, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, pregelatinized starch, sodium saccharin, talc, titanium dioxide nactive ingredients

Purpose Acid reducer

Active ingredient (in each tablet)

Drug Facts

Famotidine USP 20 mg

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

Tips for Managing Heartburn

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

Do not lie flat or bend over after eating

Do not wear tight-fitting clothing around the stomach

Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods,

chocolate, caffeine, alcohol, and certain fruits and vegetables

Raise the head of your bed Do not eat before bedtime

NDC 25000-124-68 Compare to the active ingredient in Maximum Strength Pepcid® AC† MAXIMUM STRENGTH

Famotidine Tablets USP, 20 mg

Quit smoking

Adhesive Area

If overweight, lose weight Eat slowly and avoid big meals

Acid Reducer

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



Marksans 🍑



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

Mfg. Lic. No.:GO/DRUGS/515 Verna, Goa-403722, India

<u>Г</u>ОТ:

EXP.:

Varnish Omit Area



FAMOTIDINE 20 MG

famotidine 20 mg tablet, coated

Product Information NDC:25000-124 **Product Type** HUMAN OTC DRUG Item Code (Source) **ORAL Route of Administration**

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
FAMOTIDINE (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8)	FAMOTIDINE	20 mg	

Inactive Ingredients	
Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
STARCH, CORN (UNII: O8232NY3SJ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics				
Color	WHITE	Score	no score	
Shape	ROUND	Size	8mm	
Flavor	MINT	Imprint Code	124	
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:25000-124- 94	5 in 1 CARTON	05/23/2025	
1		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:25000-124- 84	1 in 1 CARTON	05/23/2025	
2		25 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:25000-124- 68	300 in 1 BOTTLE; Type 0: Not a Combination Product	05/23/2025	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA217543	05/23/2025		

Labeler - MARKSANS PHARMA LIMITED (925822975)

Establishment					
Name	Address	ID/FEI	Business Operations		
MARKSANS PHARMA LIMITED		925822975	MANUFACTURE(25000-124)		

Revised: 5/2025 MARKSANS PHARMA LIMITED