

MAXIMUM STRENGTH ACID REDUCER- famotidine tablet
TIME CAP LABORATORIES,INC

Famotidine Tablets USP, 20mg

Drug Facts

Active ingredient (in each tablet)

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

- 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

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

Questions or comments? Call **1-877-290-4008**

Drug Facts (continued)

- 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
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Questions or comments? Call 1-877-290-4008

■ **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

Adhesive Area

Inside

1/16" Margin

NDC 49483-720-01

timelyTM

¹Compare to the active ingredient in Maximum Strength Pepcid[®] AC

Maximum Strength Acid Reducer
Famotidine Tablets USP, 20 mg

Just One Tablet Prevents & Relieves Heartburn Due to Acid Indigestion

100 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

Drug Facts

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Famotidine USP 20 mg.....Acid reducer

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- with other acid reducers

Drug Facts (continued under label)

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

Distributed by:

Time-Cap Labs, Inc.

7 Michael Avenue,

Farmingdale, NY 11735

720R 0224

Made in India



PEEL HERE

LOT:

EXP.:

Varnish Omit Area

Drug Facts (continued)

Ask a doctor or pharmacist 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.
- trrequent chest pain
- trrequent wheezing, particularly with heartburn.
- unexplained weight loss
- rashes or vomiting
- stomach pain
- kidney disease

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Stop use and ask a doctor if

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Inactive ingredients

carboxymethylcellulose sodium salt, hydroxypropylcellulose, hypromellose, magnesium stearate, microcrystalline cellulose, pregelatinized starch, talc, titanium dioxide

Questions or comments? Call 1-877-296-4008

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

Tips for Managing Heartburn

- Don't lie flat or bend over after eating
- Don't wear tight-fitting clothing around the stomach
- Don't eat before bedtime
- Raise the head of your bed
- Avoid alcohol, undergarments and belts
- Eat slowly and avoid big meals
- Overweight, lose weight
- Quit smoking

Adhesive Area

NDC 49483-720-20

timely™

*Compare to the active ingredient in Maximum Strength Pepcid® AC

Maximum Strength Acid Reducer
Famotidine Tablets USP, 20 mg

Just One Tablet Prevents & Relieves Heartburn Due to Acid Indigestion

200 TABLETS

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Distributed by:
Time-Cap Labs, Inc.
7 Michael Avenue
Farmingdale, NY 11735
720R-0423
Made in India

Lot No.:
Exp Date:

3 4 9 4 8 3 7 2 0 2 0 4

Varnish Omit Area

PEEL HERE

MAXIMUM STRENGTH ACID REDUCER

famotidine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49483-720
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FAMOTIDINE (UNII: 5QZ015J2Z8) (FAMOTIDINE - UNII:5QZ015J2Z8)	FAMOTIDINE	20 mg

Inactive Ingredients

Ingredient Name	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)

HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)

TALC (UNII: 7SEV7J4R1U)

MAGNESIUM STEARATE (UNII: 70097M6130)

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)

STARCH, CORN (UNII: O8232NY3SJ)

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-720-20	200 in 1 BOTTLE; Type 0: Not a Combination Product	06/15/2023	
2	NDC:49483-720-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/11/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA217543	06/15/2023	

Labeler - TIME CAP LABORATORIES,INC (037052099)

Registrant - TIME CAP LABORATORIES,INC (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(49483-720)

Revised: 3/2024

TIME CAP LABORATORIES,INC