

**FAMOTIDINE- famotidine tablet, film coated**  
**GLENMARK THERAPEUTICS INC., USA**

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**Famotidine Tablets**

**Drug Facts**

**Active ingredient (in each tablet)**

Famotidine, USP 10 mg and 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:
  - o to **relieve** symptoms, swallow 1 tablet with a glass of water. Do not chew.
  - o to **prevent** symptoms, swallow 1 tablet (of 10 mg) with a glass of water at any time from **15 to 60 minutes before** eating food or drinking beverages that cause heartburn
  - o to **prevent** symptoms, swallow 1 tablet (of 20 mg) with a glass of water at any time from **10 to 60 minutes before** eating food or drinking beverages that cause heartburn
  - o **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°C to 25°C (68°F to 77°F)
- protect from moisture

## Inactive ingredients

Microcrystalline Cellulose, Pre-gelatinized Starch, Sodium Starch glycolate, Hydroxypropyl Cellulose, Magnesium stearate, Hypromellose, Titanium dioxide, Triacetin, Talc, Macrogol

## Questions or comments?

Call us at **1 (888) 721-7115 (toll-free)**

**Distributed by: Glenmark Therapeutics Inc., USA**

Mahwah, NJ 07430

Made in India

M.L. No.: 02/SKL/AP/2015/F/R

Revision: 04/22

## Principal Display Panel

**NDC 72657-112-90**

**Famotidine Tablets, USP 10mg**

**90 Tablets**



NDC 72657-112-90

**ORIGINAL STRENGTH**

**FAMOTIDINE**  
**TABLETS, USP 10 mg**

**ACID REDUCER**

†Compare to the active ingredient in Pepcid AC®

**JUST ONE TABLET!**

Prevents & Relieves Heartburn Due to Acid Indigestion

ACTUAL SIZE



**90**  
**TABLETS**

**glenmark**  
Therapeutics

**Drug Facts**

Active ingredient (in each tablet)	Purpose
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**

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**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.

**Drug Facts (continued)**

**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.**

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**Directions**

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

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- store at 20°C to 25°C (68°F to 77°F)
- protect from moisture

**Inactive ingredients**

Microcrystalline Cellulose, Pre-gelatinized Starch, Sodium Starch glycolate, Hydroxypropyl Cellulose, Magnesium stearate, Hypromellose, Titanium dioxide, Triacetin, Talc, Macrogol

**Questions or Comments?**

Call us at 1 (888) 721-7115

**Do not use if printed foil seal on bottle is broken or missing.**

**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

†This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of PEPICID AC® nor by McNeil Consumer Pharmaceuticals Co., owner of the registered trademarks PEPICID® and PEPICID AC® [Neither Johnson & Johnson nor McNeil CPC make or license Glenmark's product].

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04/22



N 3117265711129011

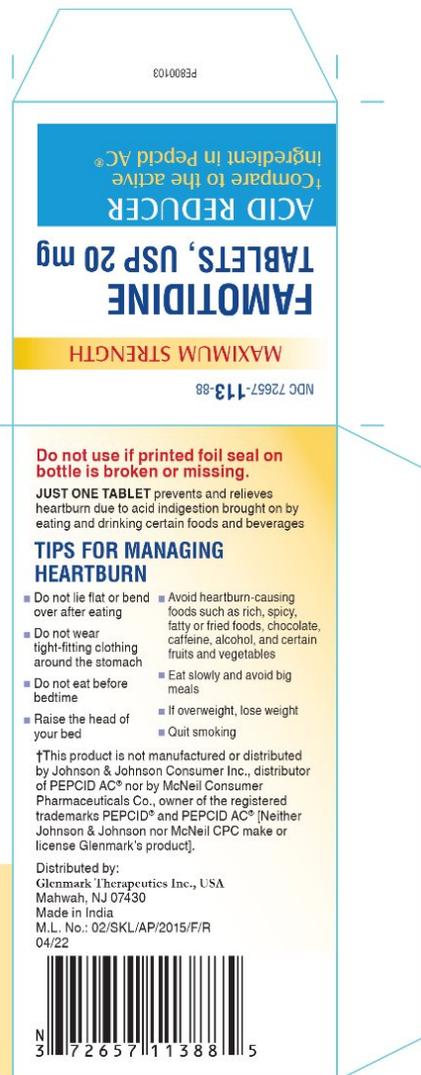
UNVARNISHED AREA  
42 mm x 42 mm FOR  
LOT & EXP.

# Principal Display Panel

NDC 72657-113-88

Famotidine Tablets, USP 20mg

85 Tablets



NDC 72657-113-88

**MAXIMUM STRENGTH**

**FAMOTIDINE TABLETS, USP 20 mg**

**ACID REDUCER**

†Compare to the active ingredient in Pepcid AC®

**JUST ONE TABLET!**

Prevents & Relieves Heartburn Due to Acid Indigestion

**85 TABLETS**

**glenmark Therapeutics**

ACTUAL SIZE

**Drug Facts**

Active ingredient (in each tablet)	Purpose
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**

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- with other acid reducers

**Ask a doctor before use if you have**

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- 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
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- frequent wheezing, particularly with heartburn
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- 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.

**Drug Facts (continued)**

**Stop use and ask a doctor if** your heartburn continues or worsens or 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°C to 25°C (68°F to 77°F)
- protect from moisture

**Inactive ingredients**

Microcrystalline Cellulose, Pre-gelatinized Starch, Sodium Starch glycolate, Hydroxypropyl Cellulose, Magnesium stearate, Hypromellose, Titanium dioxide, Triacetin, Talc, Macrogol

**Questions or Comments?**  
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UNVARNISHED AREA  
42 mm x 42 mm FOR  
LOT & EXP.

famotidine tablet, film coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72657-112
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>FAMOTIDINE</b> (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8)	FAMOTIDINE	10 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>SODIUM STARCH GLYCOLATE TYPE A</b> (UNII: H8AV0SQX4D)	
<b>HYDROXYPROPYL CELLULOSE (110000 WAMW)</b> (UNII: 5Y0974F5PW)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>HYPROMELLOSE 2910 (6 MPA.S)</b> (UNII: 0WZ8WG20P6)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	
<b>POLYETHYLENE GLYCOL 4000</b> (UNII: 4R4HFI6D95)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	

## Product Characteristics

<b>Color</b>	WHITE (white to off-white)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	5mm
<b>Flavor</b>		<b>Imprint Code</b>	V;21
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:72657-112-90	1 in 1 CARTON	06/01/2022	
1		90 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:72657-112-20	1 in 1 CARTON	06/01/2022	
2		200 in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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ANDA	ANDA215822	06/01/2022	
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## FAMOTIDINE

famotidine tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72657-113
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>FAMOTIDINE</b> (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8)	FAMOTIDINE	20 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>SODIUM STARCH GLYCOLATE TYPE A</b> (UNII: H8AV0SQX4D)	
<b>HYDROXYPROPYL CELLULOSE (110000 WAMW)</b> (UNII: 5Y0974F5PW)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>HYPROMELLOSE 2910 (6 MPA.S)</b> (UNII: 0WZ8WG20P6)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	
<b>POLYETHYLENE GLYCOL 4000</b> (UNII: 4R4HFI6D95)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	

### Product Characteristics

<b>Color</b>	WHITE (white to off-white)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	6mm
<b>Flavor</b>		<b>Imprint Code</b>	V;15
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72657-113-88	1 in 1 CARTON	06/01/2022	
1		85 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:72657-113-20	1 in 1 CARTON	06/01/2022	
2		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	ANDA215822	06/01/2022	

**Labeler** - GLENMARK THERAPEUTICS INC., USA (969085666)

## Establishment

Name	Address	ID/FEI	Business Operations
VKT Pharma Private Limited		871408062	MANUFACTURE(72657-112, 72657-113)

Revised: 5/2022

GLENMARK THERAPEUTICS INC., USA