PEPCID AC MAXIMUM STRENGTH- famotidine tablet, film coated
Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division

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PEPCID® AC
Maximum Strength

Drug Facts

Active ingredient (in each tablet)

Famotidine 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

Inactive ingredients

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

Questions or comments?

1-800-755-4008 (toll-free) or **215-273-8755** (collect)

PRINCIPAL DISPLAY PANEL

See New Warnings

NDC 16837-855-14

MAXIMUM STRENGTH

Pepcid®
AC

Famotidine Tablets 20 mg
Acid Reducer

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

actual size

25 Tablets

MAXIMUM STRENGTH

Pepcid® AC

25 Tablets

See New Warnings

NDC 16837-855-14

MAXIMUM STRENGTH

Pepcid® AC

Famotidine Tablets 20 mg
Acid Reducer

Just One Tablet!

Prevents & Relieves Heartburn Due to Acid Indigestion

300455058

300455058

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MAXIMUM STRENGTH

Pepcid® AC

Famotidine (active ingredient) made in Hungary.
Processed in Canada
Distributed by: JOHNSON & JOHNSON CONSUMER INC.
McNeil Consumer Healthcare Division
Fort Washington, PA 19034 USA

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MAXIMUM STRENGTH

Pepcid® AC

Do not use if blister unit is torn or broken

- 1 tablet relieves heartburn due to acid indigestion
- PEPCID AC® prevents heartburn due to acid indigestion brought on by eating and drinking certain foods and beverages.

Drug Facts

Active ingredient (in each tablet)	Purpose
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 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.

Drug Facts (continued)

- 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)

Drug Facts (continued)

- read the directions and warnings before use

Other information

- do not use more than 2 tablets in 24 hours
- children under 12 years: ask a doctor
- cause heartburn

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

Drug Facts (continued)

- keep the carton. It contains important information.
- store at 20°-25°C (68°-77°F)
- protect from moisture

Inactive ingredients

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

Questions or comments?

1-800-755-4008 (toll-free) or **215-273-8755** (collect)

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

PEPCID AC MAXIMUM STRENGTH

famotidine tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:16837-855
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)	
HYDROXYPROPYL CELLULOSE (90000 WAMW) (UNII: UKE75GEA7F)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
magnesium stearate (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
talc (UNII: 7SEV7J4R1U)	
titanium dioxide (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	WHITE	**Score**	no score
Shape	SEMI-CIRCLE (D shaped)	**Size**	9mm
Flavor		**Imprint Code**	PAC;20
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:16837-855-05	1 in 1 CARTON	09/01/2003	
1		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:16837-855-25	5 in 1 CARTON	09/01/2003	03/31/2014
2		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:16837-855-49	1 in 1 CARTON	09/01/2003	

3		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:16837-855-50	1 in 1 CARTON	09/01/2003	
4		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
5	NDC:16837-855-52	50 in 1 TRAY	09/01/2003	
5		1 in 1 POUCH; Type 0: Not a Combination Product		
6	NDC:16837-855-65	1 in 1 CARTON	09/01/2003	
6		65 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
7	NDC:16837-855-67	1 in 1 CARTON	09/01/2003	
7		65 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
8	NDC:16837-855-70	1 in 1 CARTON	09/01/2003	
8		70 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
9	NDC:16837-855-75	1 in 1 CARTON	09/01/2003	
9		75 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
10	NDC:16837-855-80	1 in 1 CARTON	09/01/2003	
10		80 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
11	NDC:16837-855-85	1 in 1 CARTON	09/01/2003	
11		85 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
12	NDC:16837-855-09	1 in 1 PACKAGE	09/01/2003	
12		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
13	NDC:16837-855-12	1 in 1 CARTON	09/01/2003	
13		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
14	NDC:16837-855-13	1 in 1 POUCH; Type 0: Not a Combination Product	09/01/2003	
15	NDC:16837-855-14	5 in 1 CARTON	09/01/2003	
15		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
16	NDC:16837-855-15	1 in 1 CARTON	09/01/2003	
16		35 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
17	NDC:16837-855-17	1 in 1 CARTON	09/01/2003	
17		65 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
18	NDC:16837-855-18	1 in 1 CARTON	09/01/2003	
18		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
19	NDC:16837-855-	5 in 1 CARTON	09/01/2003	

19	40	5 in 1 CARTON	09/01/2003	
19		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
20	NDC:16837-855-51	12 in 1 CARTON	09/01/2003	
20		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
21	NDC:16837-855-16	1 in 1 CARTON	09/01/2003	
21		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
22	NDC:16837-855-20	2 in 1 PACKAGE	08/22/2014	
22	NDC:16837-855-16	1 in 1 CARTON		
22		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
23	NDC:16837-855-19	1 in 1 CARTON	04/27/2015	
23		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020325	09/01/2003	

Labeler - Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division (878046358)

Revised: 3/2020 Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division