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

Pepcid AC Original Strength

Drug Facts

Active ingredient (in each tablet)

Famotidine 10 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 **15 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, red iron oxide, talc, titanium dioxide

Questions or comments?

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

PRINCIPAL DISPLAY PANEL

See New Warnings

NDC 16837-872-20

ORIGINAL STRENGTH

Pepcid_®

AC

Famotidine Tablets 10 mg

Acid Reducer

Just One Tablet!

Prevents & Relieves Heartburn

Due to Acid Indigestion

actual size

30 Tablets



- food or drinking bevera gesthat cause heartburn do notuse more than 2 tablets in 24 hours
- o **preve nt** symptoms, swallow 1 tablet with a glass of
- ofwater. Do not chew. edults and children 12 years and over: • to relieve symptoms, swallow 1 tablet with a glass

Drug Facts (continued)

Directions

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Orug Facts (continued)

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• relieves hear aburn as socia ted with acid in diges fron s as N

Acid reducer emotidine 10 mg (in each tablet) Purpose Active in gredient

Drug Facts

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Drug Facts (continued)

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beverages.

ind gestion brought on by eating and drinking certain foods and • JUST ONE TABLET prevents and relieves heartburn due to acid

Do notuse if blister unitistorn or broken

ORIGINAL STRENGTH

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30 Tablets



NDC 16837-872-20

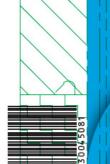
ORIGINAL STRENGTH

Famotidine Tablets 10 mg Acid Reducer

Just One Tablet!

Prevents & Relieves Heartburn Due to Acid Indigestion





PEPCID AC ORIGINAL STRENGTH

famotidine tablet, film coated

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Pro	auct	Information	

Product Type HUMAN OTC DRUG Item Code (Source) NDC:16837-872

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Famotidine (UNII: 5QZO15J2Z8) (Famotidine - UNII:5QZO15J2Z8)	Famotidine	10 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)			
FERRIC OXIDE RED (UNII: 1K09F3G675)			
talc (UNII: 7SEV7J4R1U)			
titanium dioxide (UNII: 15FIX9 V2JP)			

Product Characteristics				
Color	PINK (pale rose)	Score	no score	
Shape	SQUARE (rounded edges)	Size	7mm	
Flavor		Imprint Code	PEPCID;AC	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:16837-872- 10	1 in 1 CARTON	0 1/2 1/2 0 11		
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product			
2	NDC:16837-872- 30	3 in 1 CARTON	10/01/1995		
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product			
	NDC-10007 070				

31	4 in 1 CARTON	10/01/1995	
	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
NDC:16837-872- 60	1 in 1 CARTON	10/01/1995	
	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
NDC:16837-872- 90	1 in 1 CARTON	10/01/1995	
	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
NDC:16837-872- 20	3 in 1 CARTON	0 1/2 1/2 0 11	
	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
NDC:16837-872- 22	1 in 1 CARTON	0 1/2 1/2 0 11	
	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
	31 NDC:16837-872- 60 NDC:16837-872- 90 NDC:16837-872- 20 NDC:16837-872-	31 10 in 1 BLISTER PACK; Type 0: Not a Combination Product NDC:16837-872- 60 1 in 1 CARTON 60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product NDC:16837-872- 90 1 in 1 CARTON 90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product NDC:16837-872- 20 3 in 1 CARTON 10 in 1 BLISTER PACK; Type 0: Not a Combination Product NDC:16837-872- 21 in 1 CARTON 90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product NDC:16837-872- 22 90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination	10 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	10/01/1995		

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

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