

MAXIMUM STRENGTH PEPCID AC ICY COOL MINT- famotidine tablet, film coated

Kenvue Brands LLC

Maximum Strength

PEPCID® AC

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, FD&C blue no. 1 aluminum lake, flavors, hypromellose 2910, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, pregelatinized starch, sucralose, talc, titanium dioxide

Questions or comments?

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

Do not use if foil inner seal imprinted with SEALED FOR YOUR SAFETY is broken or missing

PRINCIPAL DISPLAY PANEL

NDC 16837-889-40

MAXIMUM STRENGTH

Pepcid®

AC



30055656/130904

Drug Facts (continued)

- 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

- 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

Drug Facts (continued)

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

Drug Facts (continued)

- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- heartburn with lightheadedness, sweating, or dizziness
- sign of a more serious condition.
- had heartburn over 3 months. This may be a sign of a more serious condition.

Ask a doctor before use if you have

- with other acid reducers
- condition. See your doctor.
- vomiting with blood, or bloody or black stools. These may be signs of a serious condition.
- if you have trouble or pain swallowing food, or if you have trouble or pain swallowing food.

Drug Facts (continued)

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 foil inner seal imprinted with SEALED FOR YOUR SAFETY 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

Johnson & Johnson Consumer Inc.
Allendale, NJ 07005
Pharmaceuticals Division
19034 USA
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MAXIMUM STRENGTH PEPCID AC ICY COOL MINT

famotidine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:16837-889
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
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TALC (UNII: 7SEV7J4R1U)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	

SUCRALOSE (UNII: 96K6UQ3ZD4)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

Product Characteristics

Color	blue	Score	no score
Shape	FREEFORM	Size	9mm
Flavor		Imprint Code	PAC;20
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16837-889-20	1 in 1 CARTON	03/11/2024	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:16837-889-40	1 in 1 CARTON	03/11/2024	
2		40 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020325	03/11/2024	

Labeler - Kenvue Brands LLC (118772437)

Revised: 11/2024

Kenvue Brands LLC