

CENTER FOR DRUG EVALUATION AND RESEARCH



APPLICATION NUMBER: 020902

PRINTED LABELING

Drug Facts
Active ingredient (in each gelcap)
Famotidine 10mg
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
Do not use
• if you have trouble swallowing
• with other acid reducers
Stop use and ask a doctor if
• stomach pain continues
• 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.
Directions
• adults and children 12 years and over:
• to prevent symptoms, swallow 1 gelcap 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 gelcaps in 24 hours
• if you are under 12 years, ask a doctor



Pepcid AC
Gelcaps

Do not use if the individual blister unit is open or torn.
• 1 gelcap relieves heartburn due to acid indigestion (Read Package insert before use).
• PEPCID AC prevents heartburn due to acid indigestion brought on by eating and drinking certain foods and beverages.

Pepcid AC FREE **Pepcid AC** Offer
Gelcaps (Mail-in offer. See details inside.)

NEW! GELCAPS
Pepcid AC
Famotidine Tablets 10mg/Acid Reducer®

Gelcaps

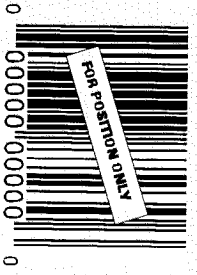
Relieves & Prevents Heartburn Due To Acid Indigestion

30 Gelcaps (Gelatin Coated, Capsule Shaped Tablets) **Just One Per Dose**

LOT AND EXP. DATE
STAMPED HERE

Pepcid AC
Gelcaps

Distributed by:
Johanson • Johnson • MERCK
CONSUMER PHARMACEUTICALS CO.
FORT WASHINGTON, PA 19034 USA
If You Have Questions Or Comments:
Please Call 1-800-755-4008



Drug Facts (continued)

Other information
• keep the carton and package insert. They contain important information.
• store at 25°-30°C (77°-86°F) • protect from moisture

Inactive ingredients benzyl alcohol, black iron oxide, butylparaben, castor oil, croscarmellose, hydroxypropyl methylcellulose, magnesium stearate, methylparaben, microcrystalline cellulose, pregelatinized corn starch, propylene glycol, polyparaben, sodium lauryl sulfate, sodium propionate, talc, titanium dioxide

Questions or comments? 1-800-755-4008

Do not use if the individual blister unit is open or torn.

WHAT YOU SHOULD KNOW ABOUT:

Pepcid
Famotidine Tablets 10mg/
Acid Reducer
Gelcaps

PACKAGE INSERT

A non-prescription stomach medicine

PEPCID AC Gelcaps contain a medicine, different from antacids, that doctors have prescribed for years to treat acid-related problems in millions of people.

Product Benefits: • 1 gelcap relieves heartburn due to acid indigestion.

- Pepcid AC prevents heartburn due to acid indigestion brought on by eating and drinking certain foods and beverages.
- It contains famotidine, a prescription-proven medicine.

Shown actual size

How to use PEPCID AC Gelcaps

Use PEPCID AC Gelcaps to relieve or prevent heartburn due to acid indigestion and sour stomach.

TO RELIEVE SYMPTOMS
Swallow 1 gelcap with a glass of water (do not chew).



TO PREVENT SYMPTOMS
Swallow 1 gelcap with a glass of water at any time from 15 to 60 minutes before eating food or drinking beverages that cause heartburn.



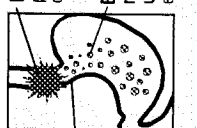
PEPCID AC can be used up to twice daily (up to 2 gelcaps in 24 hours).

Excess acid: a burning problem

It is normal for the stomach to produce acid, especially after consuming food and beverages. However, acid in the wrong place (the esophagus), or too much acid, can cause burning pain and discomfort that interfere with everyday activities.

Heartburn—Caused by acid in the esophagus

A valve-like muscle called the lower esophageal sphincter (LES) is relaxed in an open position



Burning, painful discomfort

Excess acid moves up into esophagus

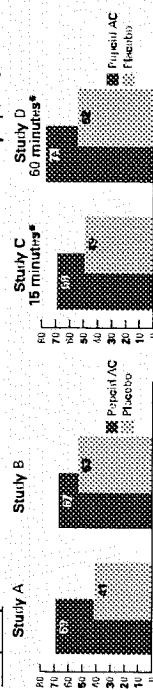
Tips for Managing Heartburn

- Do not lie flat or bend over soon after eating.
- Do not eat late at night, or just before bedtime.
- Certain foods or drinks are more likely to cause heartburn, such as rich, spicy, fatty, and fried foods, chocolate, caffeine, alcohol, and even some fruits and vegetables.
- Eat slowly and do not eat big meals.
- If you are overweight, lose weight.
- If you smoke, quit smoking.
- Raise the head of your bed.
- Wear loose fitting clothing around your stomach.

Proven effective in clinical studies

In clinical studies, PEPCID AC film-coated tablets were significantly better in relieving and preventing heartburn than placebo tablets (tablets without the medicine). PEPCID AC Gelcaps contain the same active ingredient.

Percent of heartburn episodes completely relieved



*Time taken before eating a meal that is expected to cause symptoms.

Excellent safety record

The ingredient in PEPCID AC, famotidine, has been prescribed by doctors for years to treat millions of patients safely and effectively. The active ingredient in PEPCID AC has been taken safely with many frequently prescribed medications.

Know when to see your doctor

Heartburn and acid indigestion are common, but you should stop taking PEPCID AC and see your doctor promptly if:

- You have trouble swallowing or stomach pain continues. You may have a serious condition that may need different treatment.
- You need to take this product for more than 14 days.
- **Important: Allergy alert:** Do not use if you are allergic to famotidine or other acid reducers. Do not use with other acid reducers. This product should not be given to children under 12 years old, unless directed by a doctor. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product. Keep this and all drugs out of the reach of children. In case of accidental overdose, seek professional assistance or contact a poison control center immediately.

Questions or comments?

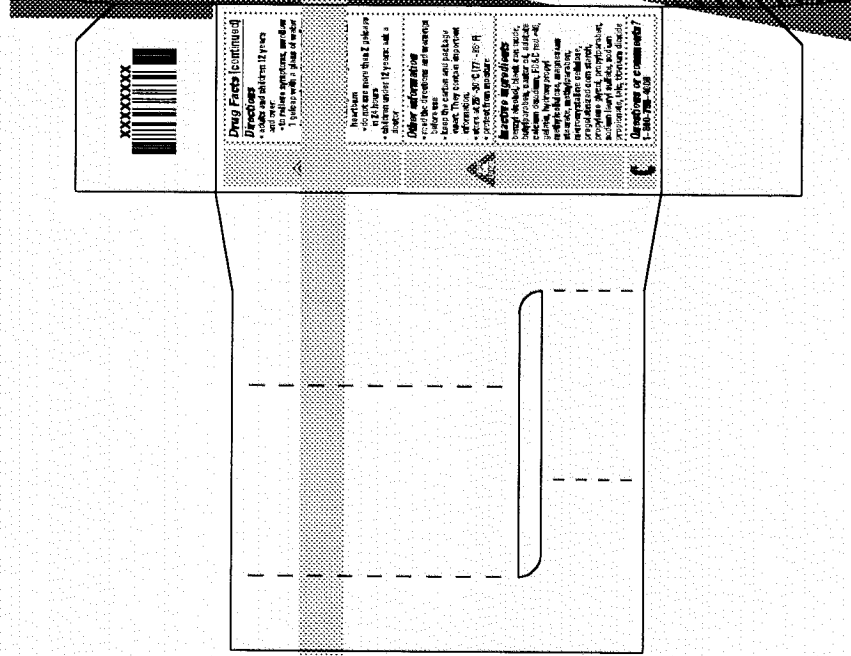
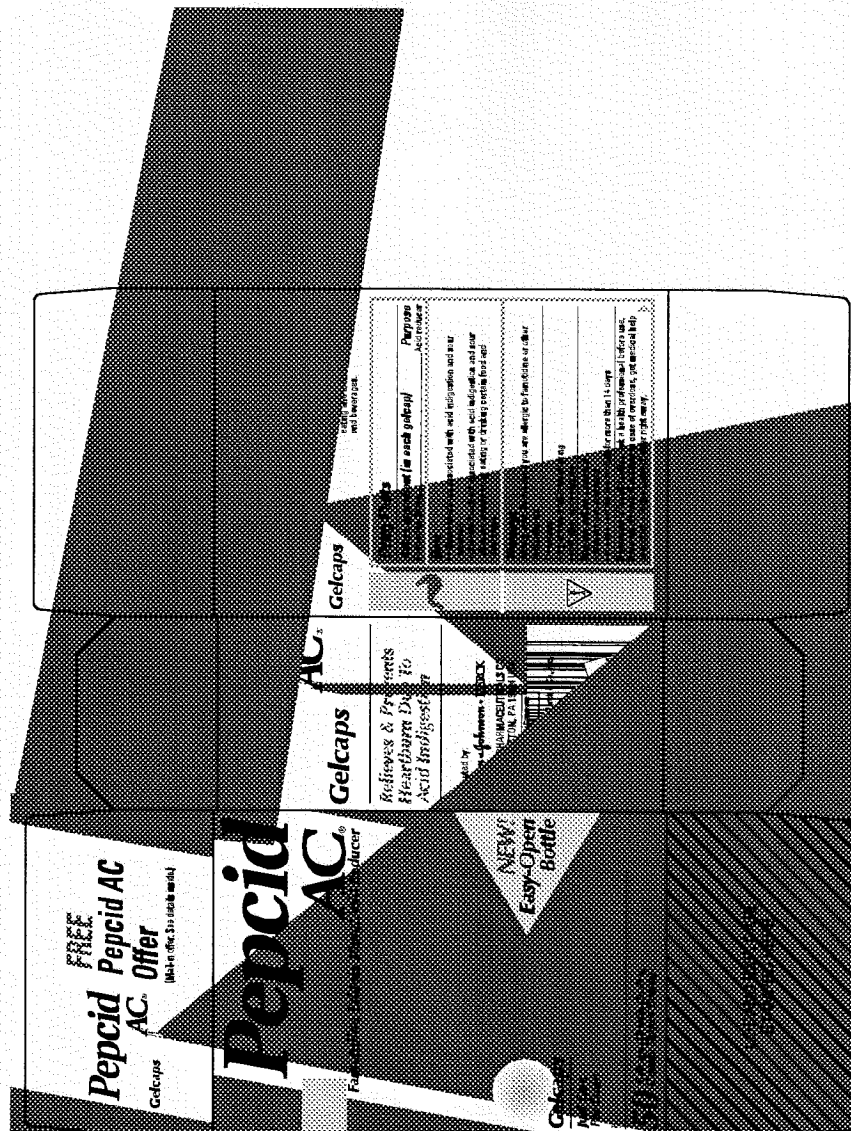


Please call 1-800-755-4008 for more information and a guide on how to help your heartburn.

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Developed by
Johnson & Johnson • MERCK
CONSUMER PHARMACEUTICALS CO.
PO BOX 100000
KENNETH SQUARE, NJ 07033 USA

COUPON

<p>PUSH BELCAP THROUGH FROM OTHER SIDE</p> <p>Pepcid AC[®] Famotidine Tablet Pung</p> <p>Dist. by J.S. HENCKS CFC R. Wash., PA 15381 USA</p> <p>EXP XX/XX LOT XXXXX</p> <p>0000000</p>	<p>PUSH BELCAP THROUGH FROM OTHER SIDE</p> <p>Pepcid AC[®] Famotidine Tablet Pung</p> <p>Dist. by J.S. HENCKS CFC R. Wash., PA 15381 USA</p> <p>EXP XX/XX LOT XXXXX</p> <p>0000000</p>	<p>PUSH BELCAP THROUGH FROM OTHER SIDE</p> <p>Pepcid AC[®] Famotidine Tablet Pung</p> <p>Dist. by J.S. HENCKS CFC R. Wash., PA 15381 USA</p> <p>EXP XX/XX LOT XXXXX</p> <p>0000000</p>	<p>PUSH BELCAP THROUGH FROM OTHER SIDE</p> <p>Pepcid AC[®] Famotidine Tablet Pung</p> <p>Dist. by J.S. HENCKS CFC R. Wash., PA 15381 USA</p> <p>EXP XX/XX LOT XXXXX</p> <p>0000000</p>	<p>PUSH BELCAP THROUGH FROM OTHER SIDE</p> <p>Pepcid AC[®] Famotidine Tablet Pung</p> <p>Dist. by J.S. HENCKS CFC R. Wash., PA 15381 USA</p> <p>EXP XX/XX LOT XXXXX</p> <p>0000000</p>
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FREE
Peppid AC Offer
Gelcaps

Peppid AC
Gelcaps

Relieves & Prevents
Heartburn, Dizziness,
Acid Indigestion

NEW!
Easy-Open
Bottle



Drug Facts (continued)
Keep out of reach of children 12 years
and under. See important information
about this medicine on the label and
package or ask your pharmacist.

Directions
Take 1 or 2 capsules 3 or 4 times a day
after meals. Do not take more than 6 capsules
in 24 hours unless directed otherwise by a
doctor.

Other important information
• Do not take if you are allergic to any of the
ingredients listed on the label.
• Do not take if you are taking other
medicines that contain cimetidine.
• Do not take if you are taking other
medicines that contain ranitidine.
• Do not take if you are taking other
medicines that contain famotidine.
• Do not take if you are taking other
medicines that contain nizatidine.
• Do not take if you are taking other
medicines that contain dexlansoprazole.
• Do not take if you are taking other
medicines that contain esomeprazole.
• Do not take if you are taking other
medicines that contain pantoprazole.
• Do not take if you are taking other
medicines that contain rabeprazole.
• Do not take if you are taking other
medicines that contain dexlansoprazole.
• Do not take if you are taking other
medicines that contain esomeprazole.
• Do not take if you are taking other
medicines that contain pantoprazole.
• Do not take if you are taking other
medicines that contain rabeprazole.

Warnings
• Do not take if you are pregnant, trying to
get pregnant, or breastfeeding.
• Do not take if you are taking other
medicines that contain cimetidine.
• Do not take if you are taking other
medicines that contain ranitidine.
• Do not take if you are taking other
medicines that contain famotidine.
• Do not take if you are taking other
medicines that contain nizatidine.
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• Do not take if you are taking other
medicines that contain esomeprazole.
• Do not take if you are taking other
medicines that contain pantoprazole.
• Do not take if you are taking other
medicines that contain rabeprazole.

Side Effects
The most common side effects of Peppid AC
Gelcaps are dizziness, headache, and
constipation. Other side effects include
nausea, heartburn, and acid indigestion.
If you experience any of these side
effects, stop taking Peppid AC Gelcaps
and call your doctor for advice.

Other information
• Peppid AC Gelcaps are available in
two strengths: 300 mg and 150 mg.
• Peppid AC Gelcaps are available in
two forms: 30 capsules and 60 capsules.
• Peppid AC Gelcaps are available in
two flavors: original and fruit.
• Peppid AC Gelcaps are available in
two colors: white and pink.

**Keep out of reach of children 12 years
and under. See important information
about this medicine on the label and
package or ask your pharmacist.**

Peppid AC Gelcaps

Relieves & Prevents
Heartburn, Dizziness,
Acid Indigestion

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Bottle

LOT AND EXP. DATE STAMPED HERE

Do not use if printed foil seal under bottle cap is open or torn.

Caution: Contains Aspirin. Avoid use if you are allergic to aspirin.

Aspirin associated with risk of bleeding. Avoid use if you are taking blood thinners or other drugs that increase the risk of bleeding. Avoid use if you are taking other drugs that increase the risk of bleeding.

Directions: For relief of heartburn, take 1 or 2 capsules 15 to 30 minutes before meals. For relief of acid indigestion, take 1 or 2 capsules 15 to 30 minutes before meals. For relief of heartburn and acid indigestion, take 1 or 2 capsules 15 to 30 minutes before meals and 1 or 2 capsules 15 to 30 minutes after meals. For relief of heartburn and acid indigestion, take 1 or 2 capsules 15 to 30 minutes before meals and 1 or 2 capsules 15 to 30 minutes after meals.

Warnings: Do not use if you are allergic to famotidine or other acid reducers. Do not use if you have trouble swallowing. Do not use if you have other acid reducers. Do not use if you are taking other drugs that increase the risk of bleeding. Do not use if you are taking other drugs that increase the risk of bleeding.

How to use: If you have trouble swallowing, ask a doctor for help. Do not use if you are taking other drugs that increase the risk of bleeding. Do not use if you are taking other drugs that increase the risk of bleeding.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. **Discontinue use** if you experience symptoms such as dizziness, lightheadedness, or fainting. **Do not use if you are pregnant or breastfeeding.** **Do not use if you are taking other drugs that increase the risk of bleeding.** **Do not use if you are taking other drugs that increase the risk of bleeding.**

LOT AND EXP. DATE

50 Gelcaps (Gelatin Coated, Capsule Shaped Tablets)

Famotidine Tablets 10mg/Acid Reducer®

Gelcaps

Relieves & Prevents Heartburn Due To Acid Indigestion

Dist. by: **Johnson & Johnson • MERCK** 0000000
 CONSUMER PHARMACEUTICALS CO. ©Registered trademark
 FORT WASHINGTON, PA 19034 USA of Merck & Co., Inc.

Do not use if printed foil seal under bottle cap is open or torn.

Active ingredients (in each gelcap):
 Famotidine 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: Allergy alert: Do not use if you are allergic to famotidine or other acid reducers

Do not use • if you have trouble swallowing
 • with other acid reducers

Stop use and ask a doctor if • stomach pain continues • you need to take this product for more than 14 days

LOT AND EXP. DATE STAMPED HERE

Pepcid

Famotidine Tablets 10mg/Acid Reducer®

Gelcaps

Relieves & Prevents Heartburn Due To Acid Indigestion

50 Gelcaps (Gelatin Coated, Capsule Shaped Tablets)

Just One Per Dose

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. **Discontinue use** if you experience symptoms such as dizziness, lightheadedness, or fainting. **Do not use if you are pregnant or breastfeeding.** **Do not use if you are taking other drugs that increase the risk of bleeding.** **Do not use if you are taking other drugs that increase the risk of bleeding.**

and over: • to relieve symptoms, swallow 1 gelcap with a glass of water • to prevent symptoms, swallow 1 gelcap 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 gelcaps in 24 hours • children under 12 years: ask a doctor

Other information: • read the directions, warnings and accompanying product information before use • keep the carton and package insert. They contain important information. • store at 25°-30°C (77°-86°F) • protect from moisture

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200%