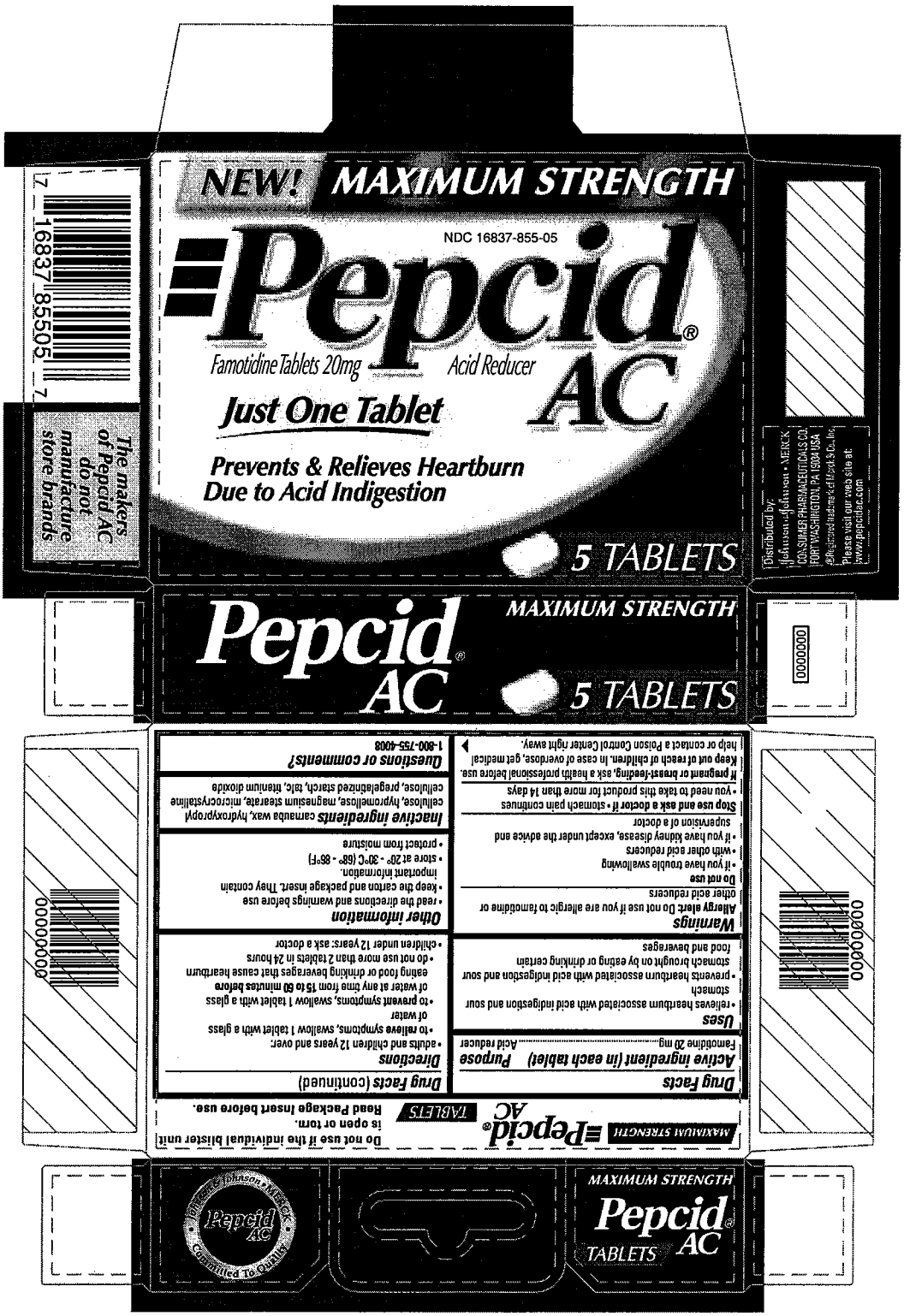
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-325 / S-015

APPROVAL LETTER

with FINAL PRINTED LABELING



Labeling Format Information:

Fonts: Universe Cond regular, bold and bold italic.

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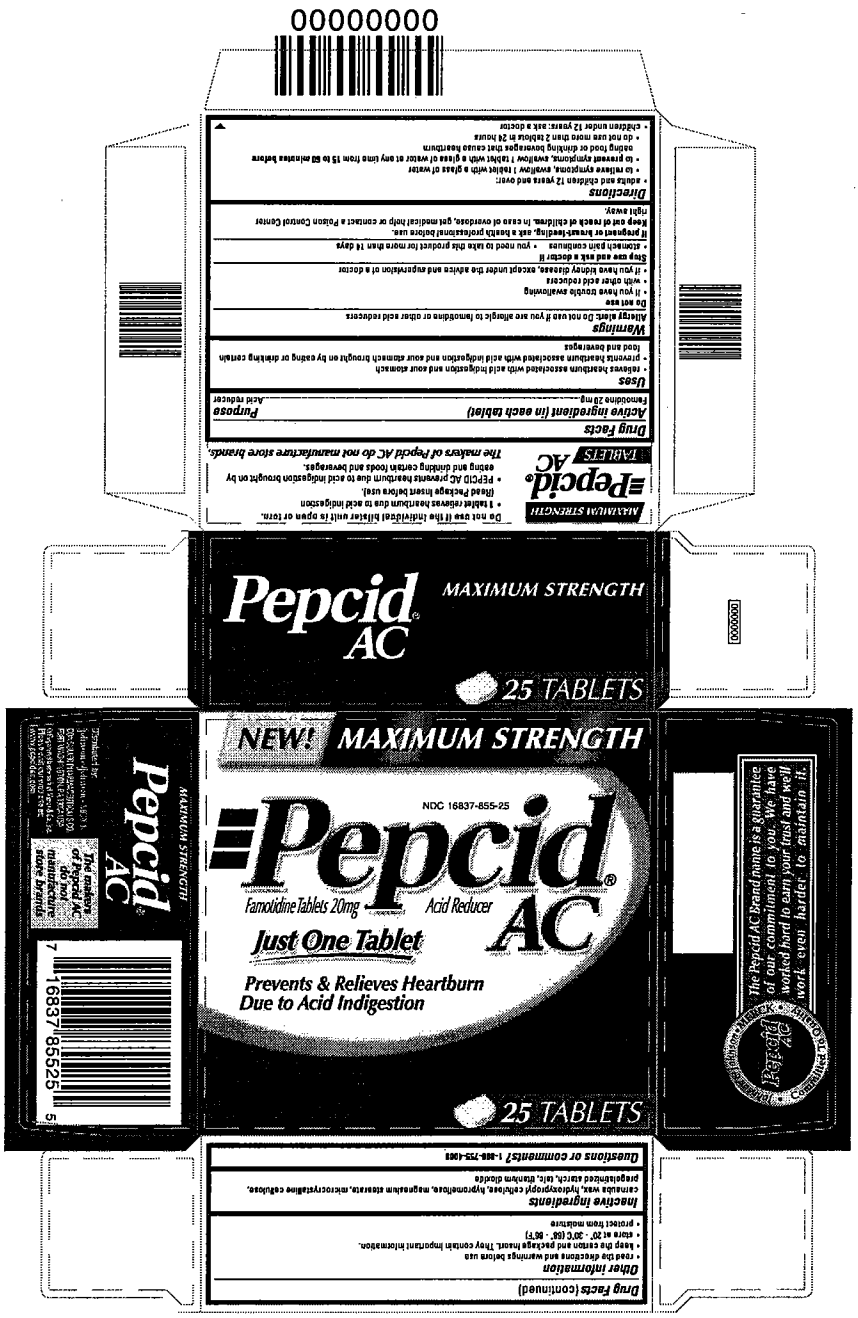
Header:	8 pt	**Bullets:**	5 pt
Subheader:	6 pt	**Barlines:**	2.5 pt
Body Text:	6 pt	**Hairlines:**	0.5 pt
Drug Facts (continued):	8 pt		

Horizontal Scale: 90% Average Kerning: 0

BLISTER CARTON PEPCID MAX STRENGTH FCT 5 (VERSION E)
3004095 A-21
JULY 17, 2003



Labeling Format Information:

Fonts: Univers Condensed regular, bold and bold oblique.

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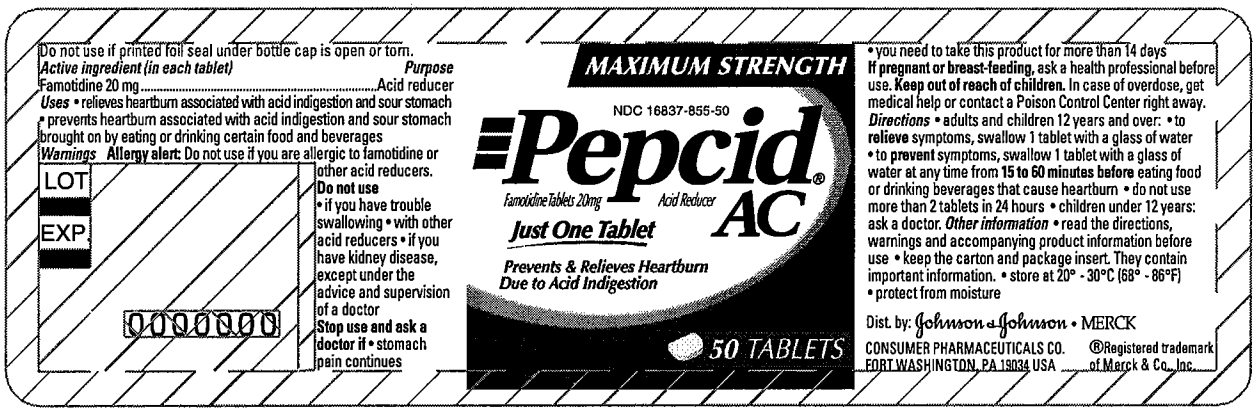
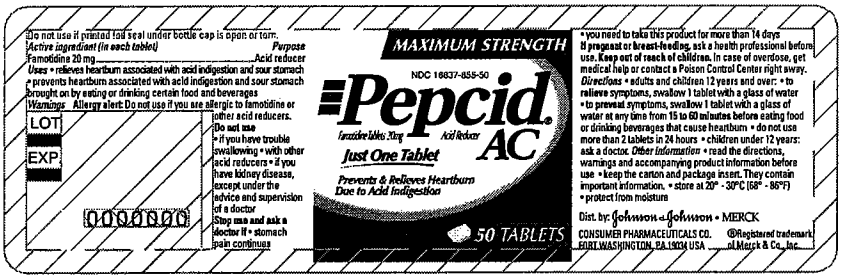
Header:	8 pt	**Bullets:**	5 pt
Subheader:	6 pt	**Barlines:**	2.5 pt
Body Text:	6 pt	**Hairlines:**	0.5 pt
Drug Facts (continued):	8 pt		

Horizontal Scale: 95% Average Kerning: 0

BLISTER CARTON PEPCID MAX STRENGTH FCT 25 (VERSION E) 3004104 D-13
JULY 17, 2003



150% OF SIZE



Labeling Format Information:

Fonts: Universe Cond regular, bold and bold italic.

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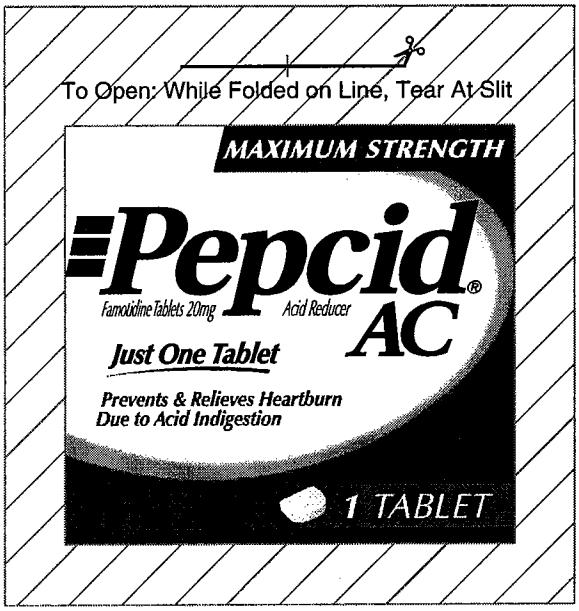
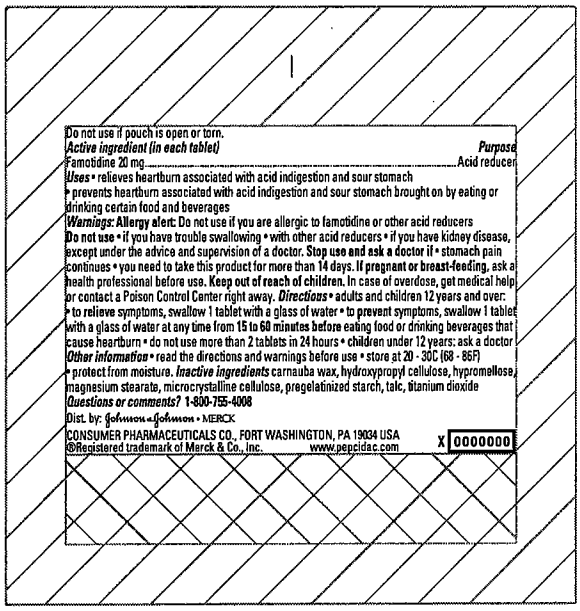
Header:	NA	**Bullets:**	4.5 pt
Subheader:	4.5 pt	**Barlines:**	NA
Body Text:	4.5 pt	**Hairlines:**	NA
Drug Facts (continued):	NA		

Horizontal Scale: 77% Average Kerning: -15

LABEL PEPCID MAX STRENGTH FCT 50 (VERSION E)
3004095 E-14
JULY 18, 2003





Do not use if pouch is open or torn.

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 swallowing • with other acid reducers • if you have kidney disease, except under the advice and supervision of a doctor. **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 relieve symptoms, swallow 1 tablet with a glass of water • 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 • store at 20 - 30C (68 - 86F) • 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

Dist. by: Johnson & Johnson • MERCK

CONSUMER PHARMACEUTICALS CO., FORT WASHINGTON, PA 19034 USA

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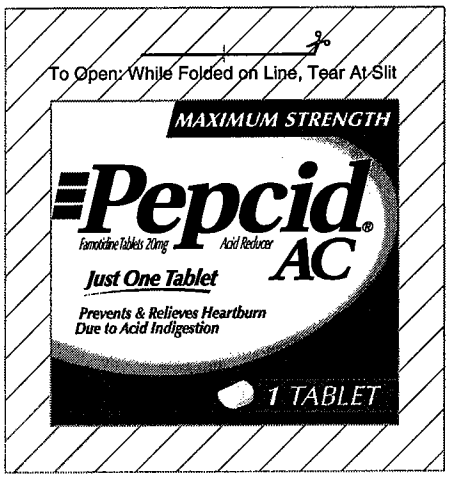
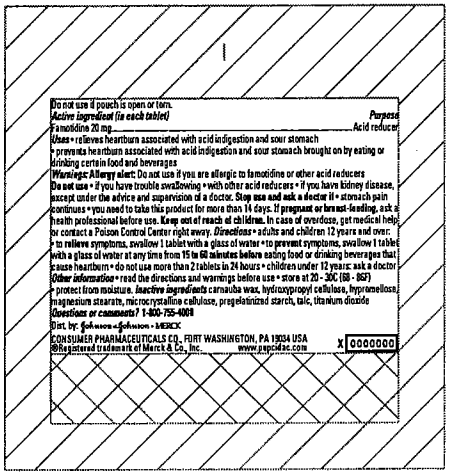
130% OF SIZE





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Labeling Format Information:

Fonts: Universe Cond regular, bold and bold italic.

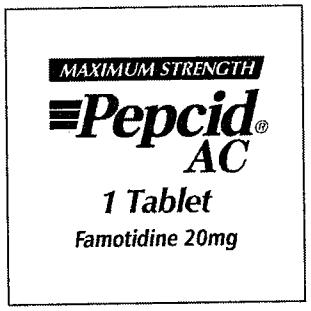
Drug Facts:	NA	**Leading:**	4.5 pt
Header:	4.5 pt	**Bullets:**	4.5 pt
Subheader:	4.5 pt	**Barlines:**	NA
Body Text:	4.5 pt	**Hairlines:**	NA
Drug Facts (continued):	NA		

Horizontal Scale: 76% Average Kerning: -4

POUCH PEPCID MAX STRENGTH FCT CR 1 (VERSION E)
3004095 G-5
JULY 17, 2003

TRADE POUCH

FRONT



BACK

PEPCID AC MAX STRENGTH TRADE POUCH
2/3/03

Labeling Format Information:

Fonts: Helvetica Neue condensed and bold condensed
Zapf Humanist 601BT bold and bold italic
Humanist 777BT bold condensed

Drug Facts:	**Leading:**
Header:	**Bullets:**
Subheader:	**Barlines:**
Body Text:	**Hairlines:**
Drug Facts (continued):	
Avg Horizontal Scale:	**Avg Kerning:**

FILE SCALE: 100%

PEPCID AC MAX STRENGTH BLISTER PKG
2/3/03

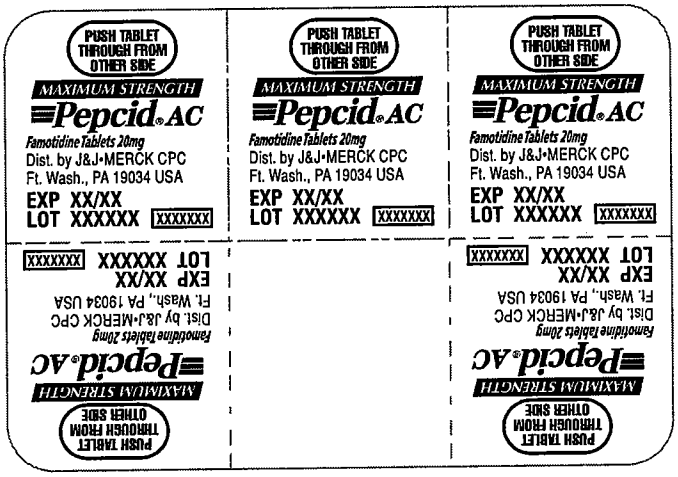
BLISTER INSIDE TRADE BOX

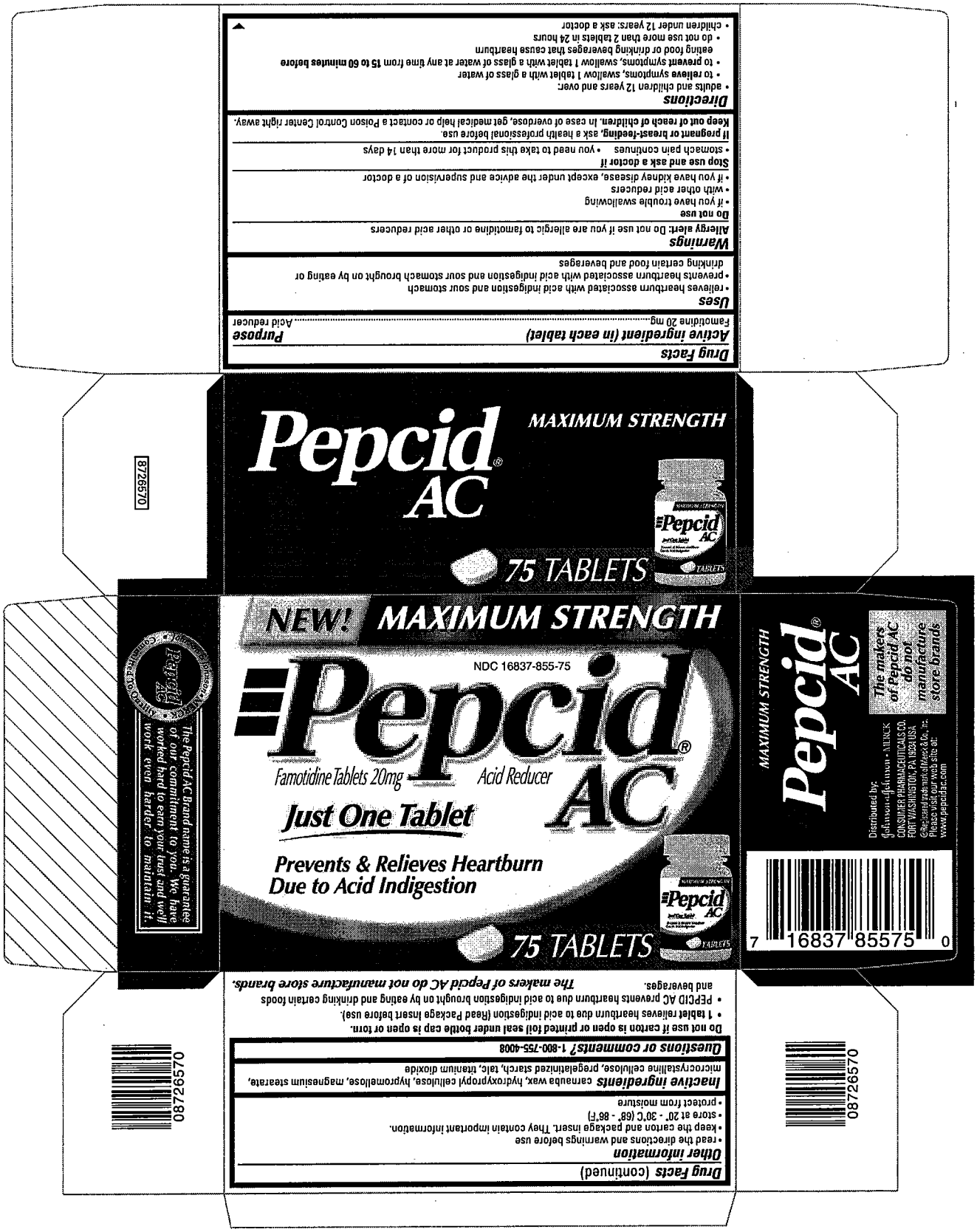
Labeling Format Information:

Fonts: Century Bold, Helvetica narrow, compressed, condensed bold, Zapf Humanist 601BT bold Humanist 777BT black italic

Drug Facts:		**Leading:**	7 pt
Header:		**Bullets:**	
Subheader:		**Barlines:**	
Body Text:	6.5 pt	**Hairlines:**	
Drug Facts (continued):			
Avg Horizontal Scale:	100%	**Avg Kerning:**	0

FILE SCALE: 100%





Labeling Format Information:

Fonts: Universe Cond regular, bold and bold italic.

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Header:	8 pt	**Bullets:**	5 pt
Subheader:	6 pt	**Barlines:**	2.5 pt
Body Text:	6 pt	**Hairlines:**	0.5 pt
Drug Facts (continued):	8 pt		

Horizontal Scale: 100% Average Kerning: 0

CTN PEPCID MAX STR 75ct CLUB CODE
3004404 A-1 JULY 30, 2003

BOTTLE CARTON PEPCID MAX STRENGTH FCT 50 (VERSION E)
3004095 C-15
JULY 18, 2003

Labeling Format Information:

Fonts: Universe Cond regular, bold and bold italic.

Drug Facts:	8.5 pt	**Leading:**	6.5 pt
Header:	8 pt	**Bullets:**	5 pt
Subheader:	6 pt	**Barlines:**	2.5 pt
Body Text:	6 pt	**Hairlines:**	0.5 pt
Drug Facts (continued):	8 pt		

Horizontal Scale: 100% Average Kerning: 0

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 swallowing
- with other acid reducers
- if you have kidney disease, except under the advice and supervision of a doctor

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 **relieve** symptoms, swallow 1 tablet with a glass of water
  - 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

Pepcid® AC
MAXIMUM STRENGTH
50 TABLETS

NEW! MAXIMUM STRENGTH
Pepcid® AC
Famotidine Tablets 20mg Acid Reducer
Just One Tablet
Prevents & Relieves Heartburn Due to Acid Indigestion
NDC 16837-855-50
50 TABLETS

Pepcid® AC
MAXIMUM STRENGTH

Drug Facts (continued)

Other information
- read the directions and warnings before use
- keep the carton and package insert. They contain important information.
- store at 20° - 30°C (68° - 86°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

Do not use if carton is open or printed foil seal under bottle cap is open or torn.
- **1 tablet** 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.

The makers of Pepcid AC do not manufacture store brands.

Pepcid® AC
MAXIMUM STRENGTH

The makers of Pepcid AC do not manufacture store brands

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www.pepcidac.com

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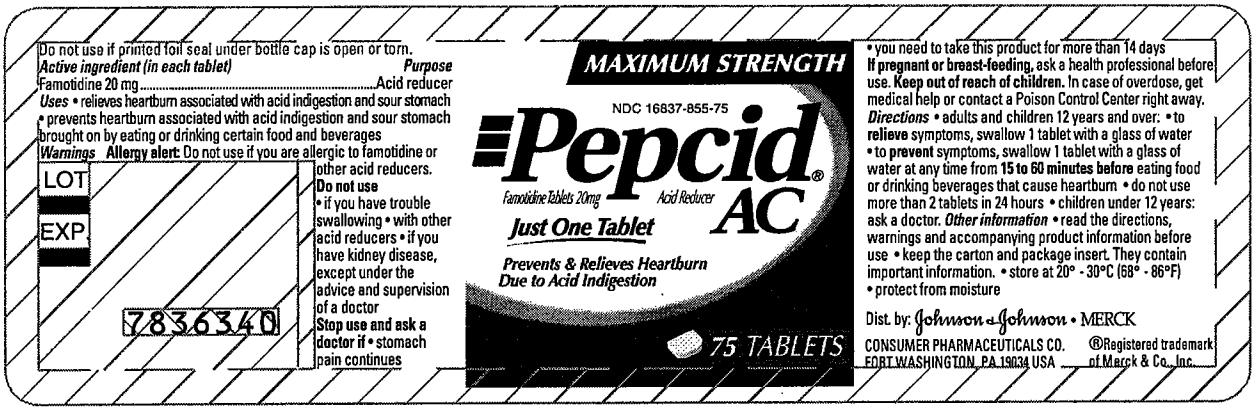
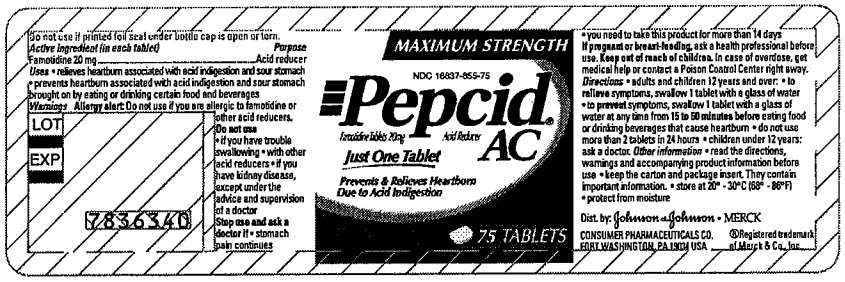


150% OF SIZE



Labeling Format Information:

Fonts: Universe Cond regular, bold and bold italic.

Drug Facts:	NA	**Leading:**	4.5 pt
Header:	NA	**Bullets:**	4.5 pt
Subheader:	4.5 pt	**Barlines:**	NA
Body Text:	4.5 pt	**Hairlines:**	NA
Drug Facts (continued):	NA		

Horizontal Scale: 77% Average Kerning: -15

LBL PEPCID MAX STR 75ct CLUB CODE 3004404 B-1 JULY 30, 2003

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

WHAT YOU SHOULD KNOW ABOUT:

MAXIMUM STRENGTH

Pepcid® AC

Famotidine Tablets 20mg/ Acid Reducer

PACKAGE INSERT

Tablets

A non-prescription stomach medicine

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

Product Benefits:

- **1 tablet** relieves heartburn due to acid indigestion.
- MAXIMUM STRENGTH PEPCID® AC prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain foods or beverages.
- It contains famotidine, a prescription-proven medicine.

Shown actual size

How to use MAXIMUM STRENGTH PEPCID® AC

Use MAXIMUM STRENGTH PEPCID® AC to relieve or prevent these symptoms:

- Heartburn
- Acid indigestion
- Sour stomach

MAXIMUM STRENGTH PEPCID® AC can be used up to twice daily (up to 2 tablets in 24 hours).

- Do not take more than 1 tablet at a time.
- Do not take more than 2 tablets in 24 hours.

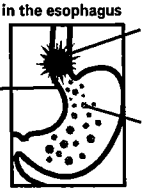
TO **RELIEVE** SYMPTOMS
Swallow 1 tablet with a glass of water (do not chew).

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.

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

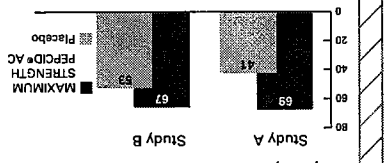


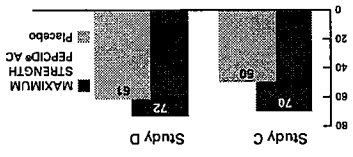
Tips for Managing Heartburn

- 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, MAXIMUM STRENGTH PEPCID®AC film-coated tablets were significantly better than placebo tablets (tablets without the medicine) in relieving and preventing heartburn.





Excellent safety record

The ingredient in MAXIMUM STRENGTH PEPCID®AC, famotidine, has been prescribed by doctors for years to treat millions of patients safely and effectively. The active ingredient in MAXIMUM STRENGTH 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 MAXIMUM STRENGTH 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.

Allergy alert: Do not use if you are allergic to famotidine or other acid reducers. Do not use with other acid reducers. Do not use if you have kidney disease, except under the advice and supervision of a doctor. 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 of how to help your heartburn.
www.pepcidac.com

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MANUFACTURER COUPON | NO EXPIRATION DATE | 00000000

Save $2.00 on your next purchase of **Pepcid® AC** any strength or **Pepcid® Complete** 25 count or larger

This coupon good only on purchase of product indicated. Any other use constitutes fraud. COUPON CANNOT BE BOUGHT, TRANSFERRED OR SOLD. LIMIT — ONE COUPON PER PURCHASE. VOID IF TAXED, RESTRICTED OR PROHIBITED BY LAW. To the retailer: Johnson & Johnson • Merck Consumer Pharmaceuticals Co. will reimburse you for the face value of this coupon plus 8¢ if submitted in compliance with Johnson & Johnson • Merck Consumer Pharmaceuticals Company Coupon Redemption Policy. Cash value 1/20th of one cent. Send coupons to Johnson & Johnson • Merck Consumer Pharmaceuticals Co., CMS Department 00045, 1 Fawcett Drive, Del Rio, TX 78840. ©JJMCP 2003.

Just ONE and heartburn's done!

0 00000 00000 0

(0000)0 00000 0000

INSERT PEPCID MAX STRENGTH FCT 5 (VERSION 3) 3004316 B-5
JULY 18, 2003

Do not use if the individual pouch is open or torn.

WHAT YOU SHOULD KNOW ABOUT:

MAXIMUM STRENGTH

Pepcid® AC

PACKAGE INSERT

Tablets

Famotidine Tablets 20mg/ Acid Reducer

A non-prescription stomach medicine

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

Product Benefits:

- **1 tablet** relieves heartburn due to acid indigestion.
- MAXIMUM STRENGTH PEPCID® AC prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain foods or beverages.
- It contains famotidine, a prescription-proven medicine.

Shown actual size

How to use MAXIMUM STRENGTH PEPCID® AC

Use MAXIMUM STRENGTH PEPCID® AC to relieve or prevent these symptoms:

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- Acid indigestion
- Sour stomach

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Heartburn — Caused by acid in the esophagus

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

Burning pain/ 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.
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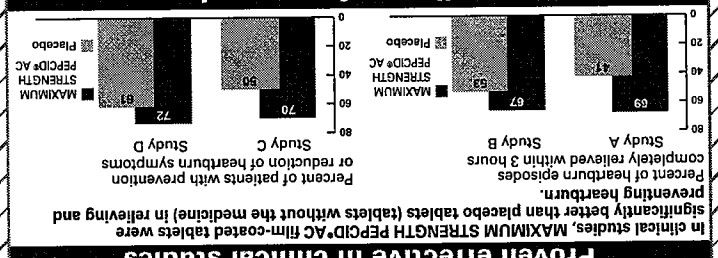

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Questions or comments?

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www.pepcidac.com

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FORT WASHINGTON, PA 19034 USA

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VALUABLE MAIL-IN OFFER

Save $3.00 on Pepcid® AC any strength or Pepcid® Complete product with purchase of 25 count or larger

Here's how you can get $3.00 off your next purchase:

BUY: Pepcid AC (any strength) or Pepcid Complete Package 25 count or Larger.

SEND: This completed certificate, UPC from the Pepcid AC or Pepcid Complete package, plus dated cash register receipt with purchase price circled.

RECEIVE: $3.00 Coupon by mail.

SEND TO: Pepcid AC / Pepcid Complete $3 Offer 780
P.O. Box 6607
Douglas, AZ 85655-6607

0000000

NOTE: Offer good only in U.S.A. and APO/FPO addresses. This request form may not be mechanically reproduced. LIMIT TWO OFFERS PER FAMILY AND/OR ADDRESS, PER YEAR. No group or organization requests will be honored. Your offer rights may not be transferred or assigned. Offer void where prohibited or taxed. You should expect to receive your coupon in 6-8 weeks. Cannot be combined with any other offers.

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Please circle one: Dr. Mr. Mrs. Miss.

Name (please print) _____

Address _____ Apt. _____

City _____ State _____ Zip _____

E-mail _____ Age: ☐ under 35 ☐ 35-49 ☐ 50-54 ☐ 55-64 ☐ 65 yrs+

INSERT PEPCID MAX STRENGTH FCT 25 (VERSION 3) 3004316 D-5
JULY 30, 2003

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

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MAXIMUM STRENGTH

Pepcid® AC

Famotidine Tablets 20mg/ Acid Reducer

PACKAGE INSERT

Tablets

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Shown actual size

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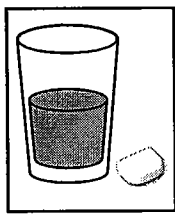
Use MAXIMUM STRENGTH PEPCID® AC to relieve or prevent these symptoms:

- Heartburn
- Acid indigestion
- Sour stomach

MAXIMUM STRENGTH PEPCID® AC can be used up to twice daily (up to 2 tablets in 24 hours).



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

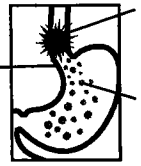
TO **PREVENT** SYMPTOMS
Swallow 1 tablet with a glass of water at any time from **15 to 60 minutes before** eating food or drinking beverages that cause heartburn.

- Do not take more than 1 tablet at a time.
- Do not take more than 2 tablets 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

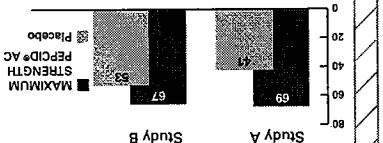


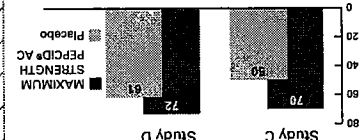
Tips for Managing Heartburn

- 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, MAXIMUM STRENGTH PEPCID®AC film-coated tablets were significantly better than placebo tablets (tablets without the medicine) in relieving and preventing heartburn.





Excellent safety record

The ingredient in MAXIMUM STRENGTH PEPCID®AC, famotidine, has been prescribed by doctors for years to treat millions of patients safely and effectively. The active ingredient in MAXIMUM STRENGTH 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 MAXIMUM STRENGTH 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.

Allergy alert: Do not use if you are allergic to famotidine or other acid reducers. Do not use with other acid reducers. Do not use if you have kidney disease, except under the advice and supervision of a doctor. 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 of how to help your heartburn.

www.pepcidac.com

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JULY 18, 2003

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/s/

Charles Ganley
9/23/03 04:12:26 PM

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