


(b) (4)

LAYOUT Z

DRAFT - FOR FDA APPROVAL

7"

5.0625"



5.0625"

2
CAPSULES

FREE 2 Day Sample And Savings!
Follow samples with a 14-day course of treatment.

TREATS FREQUENT HEARTBURN

SAMPLE – NOT FOR RETAIL SALE

Drug Facts

Active ingredient (in each capsule)	Purpose
Lansoprazole 15 mg	Acid reducer

Use

- treats frequent heartburn (occurs 2 or more days a week)
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings

Allergy alert: Do not use if you are allergic to lansoprazole

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.

Ask a doctor before use if you have

- liver disease
- 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

Ask a doctor or pharmacist before use if you are taking

- warfarin (blood-thinning medicine)
- prescription antifungal or anti-yeast medicines
- digoxin (heart medicine)
- theophylline (asthma medicine)
- tacrolimus (immune system medicine)
- atazanavir (medicine for HIV infection)

Stop use and ask a doctor if

- you get diarrhea
- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months

Drug Facts (continued)

Directions

- adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment

- swallow 1 capsule with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 capsule a day
- swallow whole. Do not crush or chew capsules.
- do not use for more than 14 days unless directed by your doctor

Repeated 14-Day Courses (if needed)

- you may repeat a 14-day course every 4 months
- do not take for more than 14 days or more often than every 4 months unless directed by a doctor
- children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.

Other information

- read the directions, warnings and all information before use
- keep the package. It contains important information.
- store at 20-25° C (68-77° F)
- keep product out of high heat and humidity
- protect product from moisture

Inactive ingredients colloidal silicon dioxide, D&C red No. 28, FD&C blue No. 1, FD&C green No. 3, FD&C red No. 40, gelatin, hydroxypropyl cellulose, low substituted hydroxypropyl cellulose, magnesium carbonate, methacrylic acid copolymer, polyethylene glycol, polysorbate 80, starch, sucrose, sugar sphere, talc, titanium dioxide

Questions or comments? 1-800-452-0051

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5.0625"

15.375"

5.0625"

2.5"

Please read all information before taking PREVACID® 24HR.

Take a 14-day course of treatment every 4 months. Do not take more than 1 course of treatment every 4 months. If you need to take this product for more than 14 days or more often than every 4 months, ask your doctor. Do not take this product for more than 14 days or more often than every 4 months unless directed by a doctor. Children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.

How to Take PREVACID® 24HR

Take 1 capsule every day for 14 days. Do not take more than 1 capsule a day. Swallow the capsule whole with a glass of water before eating in the morning. Do not crush or chew the capsule. Do not take this product for more than 14 days unless directed by your doctor.

Who Should Take PREVACID® 24HR

Adults 18 years of age and older. Do not take this product if you are pregnant or breastfeeding. If you are pregnant or breastfeeding, ask your doctor before use. Do not take this product if you are allergic to lansoprazole or any of the inactive ingredients. Do not take this product if you are taking any of the medicines listed in the "Warnings" section. Do not take this product if you are taking any of the medicines listed in the "Ask a doctor before use if you have" section. Do not take this product if you are taking any of the medicines listed in the "Ask a doctor or pharmacist before use if you are taking" section. Do not take this product if you are taking any of the medicines listed in the "Stop use and ask a doctor if" section.

Who Should Not Take PREVACID® 24HR

Do not take this product if you are allergic to lansoprazole or any of the inactive ingredients. Do not take this product if you are taking any of the medicines listed in the "Warnings" section. Do not take this product if you are taking any of the medicines listed in the "Ask a doctor before use if you have" section. Do not take this product if you are taking any of the medicines listed in the "Ask a doctor or pharmacist before use if you are taking" section. Do not take this product if you are taking any of the medicines listed in the "Stop use and ask a doctor if" section.

Who Should Talk to Their Doctor Before Taking PREVACID® 24HR

Do not take this product if you are taking any of the medicines listed in the "Warnings" section. Do not take this product if you are taking any of the medicines listed in the "Ask a doctor before use if you have" section. Do not take this product if you are taking any of the medicines listed in the "Ask a doctor or pharmacist before use if you are taking" section. Do not take this product if you are taking any of the medicines listed in the "Stop use and ask a doctor if" section.

Who Should Ask a Doctor Before Taking PREVACID® 24HR

Do not take this product if you are taking any of the medicines listed in the "Warnings" section. Do not take this product if you are taking any of the medicines listed in the "Ask a doctor before use if you have" section. Do not take this product if you are taking any of the medicines listed in the "Ask a doctor or pharmacist before use if you are taking" section. Do not take this product if you are taking any of the medicines listed in the "Stop use and ask a doctor if" section.

Who Should Stop Taking PREVACID® 24HR

Do not take this product if you are taking any of the medicines listed in the "Warnings" section. Do not take this product if you are taking any of the medicines listed in the "Ask a doctor before use if you have" section. Do not take this product if you are taking any of the medicines listed in the "Ask a doctor or pharmacist before use if you are taking" section. Do not take this product if you are taking any of the medicines listed in the "Stop use and ask a doctor if" section.

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How to Take PREVACID® 24HR

Take 1 capsule every day for 14 days. Do not take more than 1 capsule a day. Swallow the capsule whole with a glass of water before eating in the morning. Do not crush or chew the capsule. Do not take this product for more than 14 days unless directed by your doctor.

Who Should Take PREVACID® 24HR

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Who Should Talk to Their Doctor Before Taking PREVACID® 24HR

Do not take this product if you are taking any of the medicines listed in the "Warnings" section. Do not take this product if you are taking any of the medicines listed in the "Ask a doctor before use if you have" section. Do not take this product if you are taking any of the medicines listed in the "Ask a doctor or pharmacist before use if you are taking" section. Do not take this product if you are taking any of the medicines listed in the "Stop use and ask a doctor if" section.

Who Should Ask a Doctor Before Taking PREVACID® 24HR

Do not take this product if you are taking any of the medicines listed in the "Warnings" section. Do not take this product if you are taking any of the medicines listed in the "Ask a doctor before use if you have" section. Do not take this product if you are taking any of the medicines listed in the "Ask a doctor or pharmacist before use if you are taking" section. Do not take this product if you are taking any of the medicines listed in the "Stop use and ask a doctor if" section.

Who Should Stop Taking PREVACID® 24HR

Do not take this product if you are taking any of the medicines listed in the "Warnings" section. Do not take this product if you are taking any of the medicines listed in the "Ask a doctor before use if you have" section. Do not take this product if you are taking any of the medicines listed in the "Ask a doctor or pharmacist before use if you are taking" section. Do not take this product if you are taking any of the medicines listed in the "Stop use and ask a doctor if" section.

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2.5"

4.75"

15.375"

4.75"


Drug Facts
 Font Size - 8.37pt & 7.73pt
 Font - Helvetica Neue Bold Condensed & Helvetica Neue Condensed
 Stroke sizes - 1.25pt & .64pt

PPI
 Font Size - 7pt & 6pt
 Font - Myriad Pro Bold Condensed & Myriad Pro Condensed
 Leading - 10pt & 7pt

DRAFT - FOR FDA APPROVAL

7"

5.0625"



PREVACID[®] 24HR
Lansoprazole delayed-release capsules 15 mg / acid reducer

- May take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours
- Clinically Proven To Treat Frequent Heartburn

14 CAPSULES
ONE 14-DAY COURSE OF TREATMENT

Sodium Free

.25"

15.375"

5.0625"

15.375"

Relieve your frequent heartburn with
1 pill a day for 14 days

Made in
Exp. date
Lot No.

FREE.
Two days of your frequent heartburn treatment

Follow samples with a 14-day course of treatment. Read Drug Facts label before use.

.25"

TAMPER-EVIDENT INNER UNIT. DO NOT USE IF FOIL SEAL OR BLACK BAND AROUND THE CENTER OF EACH CAPSULE IS TORN OR BROKEN.


PREVACID[®] 24HR
Available at retailers nationwide

Find valuable information and special offers at: www.Prevacid24HR.com

4.75"

MANUFACTURER'S COUPON | EXPIRES XXXXXX

SAVE \$3.00
on any Prevacid[®] 24HR product



Use as directed.

030067-101093

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COUPON NOT VALID FOR PURCHASES REIMBURSED BY MEDICARE, MEDICAID, OR SIMILAR FEDERAL AND STATE PROGRAMS (INCLUDING STATE PHARMACEUTICAL ASSISTANCE PROGRAMS). COUPON NOT VALID FOR RESIDENTS OF MASSACHUSETTS IF PURCHASE IS REIMBURSED BY A HEALTH CARE INSURER. COUPON IS NOT VALID WHERE PROHIBITED OR RESTRICTED BY LAW. RETAILER: We will reimburse you for face value of coupon plus 6¢ if submitted in compliance with our redemption policy, available upon request. Cash value 1¢/2¢. Mail to: Novartis Consumer Health, CMS Dept. 00067, 1 Fairwatt Dr., Del Rio, TX 78840. Limit one coupon per purchase. ©2012 Novartis Consumer Health, Inc.

Patient Starter Pack: 2 Day Sample
Follow samples with a 14-day course of treatment

CAPSULES
2

Sodium Free

TREATS FREQUENT HEARTBURN

PROFESSIONAL SAMPLE – NOT FOR RETAIL SALE

<p>Drug Facts</p> <p>Active ingredient (in each capsule) Lansoprazole 15 mg</p> <p>Purpose Acid reducer</p> <p>Use</p> <ul style="list-style-type: none"> treats frequent heartburn (occurs 2 or more days a week) not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect <p>Warnings</p> <p>Allergy alert: Do not use if you are allergic to lansoprazole</p> <p>Do not use</p> <ul style="list-style-type: none"> 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. <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> liver disease 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 <p>Ask a doctor or pharmacist before use if you are taking</p> <ul style="list-style-type: none"> warfarin (blood-thinning medicine) prescription antifungal or anti-yeast medicines digoxin (heart medicine) theophylline (asthma medicine) tacrolimus (immune system medicine) atazanavir (medicine for HIV infection) <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> you get diarrhea your heartburn continues or worsens you need to take this product for more than 14 days you need to take more than 1 course of treatment every 4 months 	<p>Drug Facts (continued)</p> <p>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.</p> <p>Directions</p> <ul style="list-style-type: none"> adults 18 years of age and older this product is to be used once a day (every 24 hours), every day for 14 days it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours <p>14-Day Course of Treatment</p> <ul style="list-style-type: none"> swallow 1 capsule with a glass of water before eating in the morning take every day for 14 days do not take more than 1 capsule a day swallow whole. Do not crush or chew capsules. do not use for more than 14 days unless directed by your doctor <p>Repeated 14-Day Courses (if needed)</p> <ul style="list-style-type: none"> you may repeat a 14-day course every 4 months do not take for more than 14 days or more often than every 4 months unless directed by a doctor <p>children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.</p> <p>Other information</p> <ul style="list-style-type: none"> read the directions, warnings and all information before use keep the package. It contains important information. store at 20-25° C (68-77° F) keep product out of high heat and humidity protect product from moisture <p>Inactive ingredients colloidal silicon dioxide, D&C red No. 28, FD&C blue No. 1, FD&C green No. 3, FD&C red No. 40, gelatin, hydroxypropyl cellulose, low substituted hydroxypropyl cellulose, magnesium carbonate, methacrylic acid copolymer, polyethylene glycol, polysorbate 80, starch, sucrose, sugar sphere, talc, titanium dioxide</p> <p>Questions or comments? 1-800-452-0051</p>
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DRAFT: FOR FDA REVIEW

DRUG FACTS TEXT	
	TYPE SIZE/STYLE
DRUG FACTS TITLE	9.0 pt. / Helvetica Neue LT Std 77 Bold Condensed
ACTIVE INGREDIENTS LINE	6.45 pt. / Helvetica Neue LT Std 77 Bold Condensed
HEADINGS	8.0 pt. / Helvetica Neue LT Std 77 Bold Condensed
SUBHEADS	6.0 pt. / Helvetica Neue LT Std 77 Bold Condensed
BODY TEXT	6.0 pt. / Helvetica Neue LT Std 57 Condensed
BULLETS	5.0 pt. / Helvetica Neue LT Std 57 Condensed
TRACKING: 0 HORIZONTAL SCALE: 0 LEADING: 6.5 pt.	
CHARACTERS/INCH: <40	
BARLINES, HAIRLINES: 0.0069 in., 0.0208 in	

PPI TEXT	
	TYPE SIZE/STYLE
PPI TITLE	11.0 pt. / Myriad Pro Bold Condensed
HEADINGS	7.0 pt. / Myriad Pro Bold Condensed
SUBHEADS	6.0 pt. / Myriad Pro Bold Condensed
BODY TEXT	6.0 pt. / Myriad Pro Condensed
BULLETS	6.0 pt. / Myriad Pro Condensed
TRACKING: 0 HORIZONTAL SCALE: 85% LEADING: 6.5 pt.	
CHARACTERS/INCH: <40	
BARLINES, HAIRLINES: 0.0108 in	

DRAFT: FOR FDA REVIEW

Indicated for the treatment of frequent heartburn*

Instructions for patient

PREVACID®24HR is to be used once a day (every 24 hours), every day for 14 days unless otherwise directed by your doctor. Read label on back before use.

*Heartburn 2 or more days a week.

Relieve your frequent heartburn with
1 pill a day for 14 days

Follow samples with a 14-day course of treatment.
Read Drug Facts label before use.

TAMPER-EVIDENT INNER UNIT. DO NOT USE IF FOIL SEAL OR BLACK BAND AROUND THE CENTER OF EACH CAPSULE IS TORN OR BROKEN.

PREVACID®24HR
Available at retailers nationwide

Find valuable information and special offers at: www.Prevacid24HR.com

©2012 Novartis Consumer Health, Inc. Use as directed to treat frequent heartburn. May take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours. Prevacid® is a registered trademark of Takeda Pharmaceuticals North America, Inc., and is used under license. U_XXXX-XX

MANUFACTURER'S COUPON | EXPIRES 12/31/12

SAVE \$1.00

on any Prevacid®24HR product



Use as directed.

COUPON NOT VALID FOR PURCHASES REIMBURSED BY MEDICARE, MEDICAID, OR SIMILAR FEDERAL AND STATE PROGRAMS (INCLUDING STATE PHARMACEUTICAL ASSISTANCE PROGRAMS). COUPON NOT VALID FOR RESIDENTS OF MASSACHUSETTS IF PURCHASE IS REIMBURSED BY A HEALTH CARE INSURER. COUPON IS NOT VALID WHERE PROHIBITED OR RESTRICTED BY LAW. **RETAILER:** We will reimburse you for face value of coupon plus 8¢ if submitted in compliance with our redemption policy, available upon request. Cash value 1/20¢. Mail to: Novartis Consumer Health, CMS Dept. 00067, 1 Fawcett Dr., Del Rio, TX 78840. Limit one coupon per purchase. ©2012 Novartis Consumer Health, Inc.

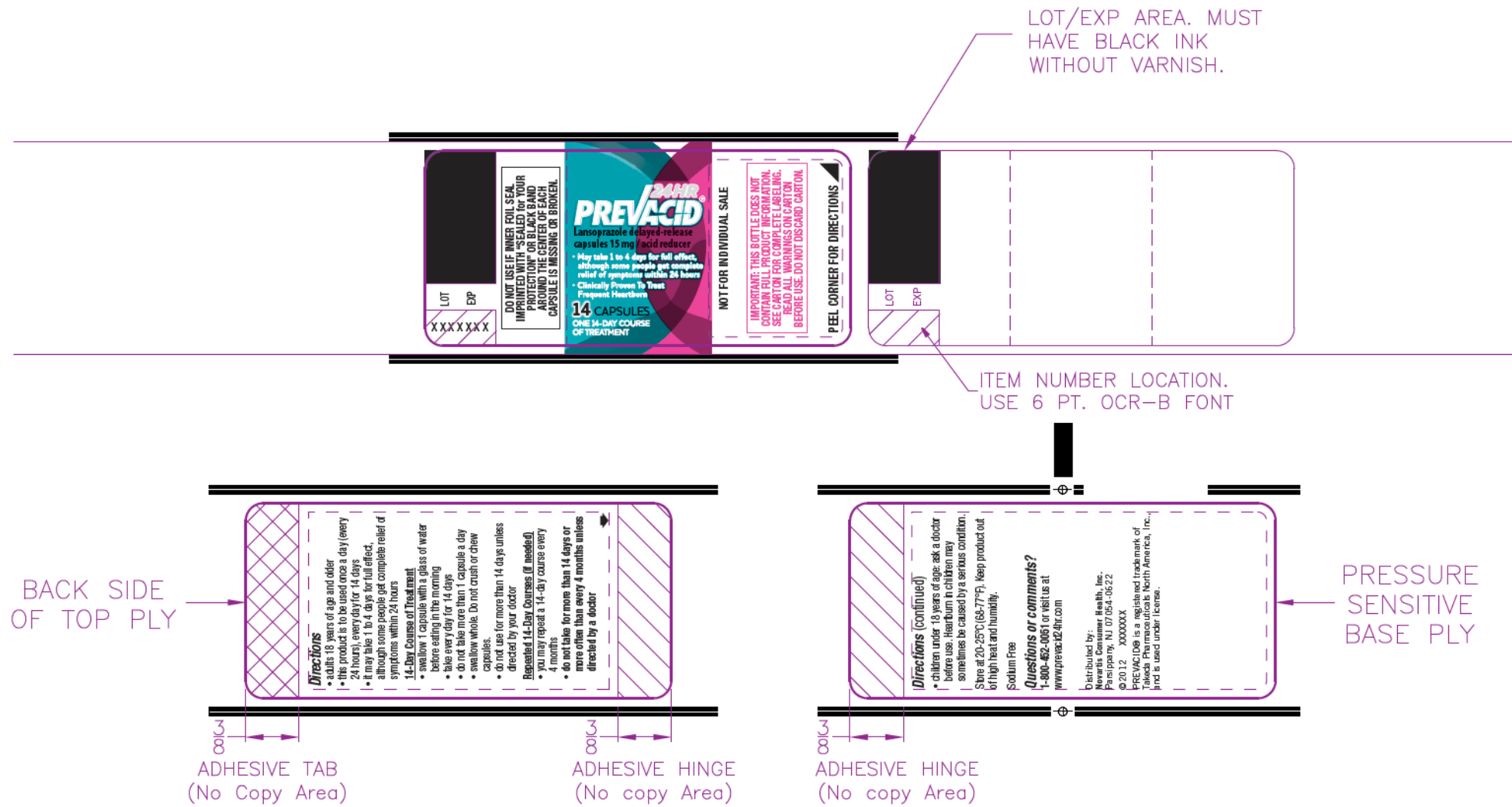


030067-101459



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FDA SUBMISSION - Prevacid 14ct Label (Humacao)







NDC 0067-6286-28

PREVACID[®]

Lansoprazole delayed-release capsules 15 mg / acid reducer

• May take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours

• Clinically Proven To Treat Frequent Heartburn



Sodium Free

Drug Facts (continued)

Other information

- read the directions, warnings and package insert before use
- keep the carton and package insert. They contain important information.
- store at 20°-25°C (68°-77°F)
- keep product out of high heat and humidity
- protect product from moisture

Inactive ingredients cobalt silicon dioxide, D&C red No. 28, FD&C blue No. 1, FD&C green No. 3, FD&C red No. 40, gelatin, hydroxypropyl cellulose, iron substituted polyacrylate, mannitol, polyethylene glycol, polyacrylic acid copolymer, polyethylene glycol, polyethylene glycol, starch, sucrose, sugar spheres, talc, titanium dioxide

Questions or comments?
1-800-462-4061
Visit us at www.prevacid24hr.com

KEEP THE CARTON AND PACKAGE INSERT. THEY CONTAIN IMPORTANT INFORMATION.

TAMPER-EVIDENT BOTTLE.
DO NOT USE IF INNER FOIL SEAL IMPRINTED WITH "SEALED FOR YOUR PROTECTION" OR BLACK BAND AROUND THE CENTER OF EACH CAPSULE IS MISSING OR BROKEN.

Drug Facts (continued)

Active ingredient (in each capsule)
Lansoprazole 15 mg

Purpose
Acid reducer

Use

- treats frequent heartburn 2 or more days a week
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings

Allergy alert: Do not use if you are allergic to lansoprazole

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.

Ask a doctor before use if you have

- liver disease
- had heartburn over 3 months. This may be a sign of a more serious condition.
- chest pain or shoulder pain with storms of breath, sweating, pain spreading to arms, neck, or shoulders; or dizziness
- frequent chest pain
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain

Ask a doctor or pharmacist before use if you are taking

- warfarin (blood-thinning medicine)
- prescription antifungal or anti-yeast medicines
- diphenhydramine (heart medicine)

Drug Facts (continued)

- theophylline (asthma medicine)
- tricyclic antidepressant medicine
- azathioprine medicine (for HIV infection)

Stop use and ask a doctor if

- you get diarrhea
- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months

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 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment

- swallow 1 capsule with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 capsule a day
- swallow whole. Do not crush or chew capsules.
- do not use for more than 14 days unless directed by your doctor

Repeat 14-Day Course (if needed)

- you may repeat a 14-day course every 4 months
- do not take for more than 14 days or more often than every 4 months unless directed by a doctor
- children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.



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DRUG FACTS TEXT

DRUG FACTS TITLE	9.0 pt. / Heibelica Condensed Bold Obl.
HEAD ING	8.0 pt. / Heibelica Condensed Bold Obl.
SUBHEADS	6.0 pt. / Heibelica Condensed Bold
BODY TEXT	6.0 pt. / Heibelica Condensed
BULLETS	5.0 pt. / Heibelica Condensed
TRACKING 0	HORIZONTAL SCALE 85% LEADING: 6.5 pt.
CHARACTERSTRIKETH: <39	
BARLINES, MARLINS:	1.5 pt., 0.5 pt.

FDA SUBMISSION - Prevacid 28ct Carton (Humacao)

NDC 0067-6286-42

PREVACID[®]

Lansoprazole delayed-release capsules 15 mg / acid reducer

• May take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours

• Clinically Proven To Treat Frequent Heartburn



42
CAPSULES

THREE 14-DAY COURSES OF TREATMENT

Sodium Free

3 BOTTLES INSIDE
42 CAPSULES TOTAL



Actual Size
ONE 14-DAY COURSE OF TREATMENT

Drug Facts (continued)

Other information

- Read the directions, warnings and package insert before use.
- Keep the carton and package insert. They contain important information.
- Store at 20-25°C (68-77°F).
- Keep product out of high heat and humidity.
- Protect product from moisture.

Inactive ingredients: colloidal silicon dioxide, D&C red No. 28, FD&C blue No. 1, FD&C green No. 3, FD&C red No. 40, gelatin, hydroxypropyl cellulose, low substituted hydroxypropyl cellulose, magnesium carbonate, methacrylic acid copolymer, polyethylene glycol, polyacrylate 90, starch, sucrose, sugar spheres, talc, titanium dioxide.

Questions or comments?
1-800-432-0061
Visit us at www.prevacid24hr.com

KEEP THE CARTON AND PACKAGE INSERT. THEY CONTAIN IMPORTANT INFORMATION.

TAMPER-EVIDENT BOTTLE
DO NOT USE IF THE BOTTLE SEAL IS IMPAIRED OR IF THERE IS ANY CRACKING OR BREAKING OF BLACK RING AROUND THE CENTER OF EACH CAPSULE IS MISSING OR BLOWN.

Drug Facts (continued)

Other information

- theophylline (asthma medicine)
- tacrolimus (immune system medicine)
- atazanavir (medicine for HIV infection)

Stop use and ask a doctor if:

- you get dizziness
- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months

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 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment

- swallow 1 capsule with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 capsule a day
- swallow whole. Do not crush or chew capsules.
- do not use for more than 14 days unless directed by your doctor

Repeated 14-Day Courses (if needed)

- you may repeat a 14-day course every 4 months
- do not take for more than 14 days or more often than every 4 months unless directed by a doctor
- children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.

Drug Facts

Active ingredient (in each capsule)
Lansoprazole 15 mg (acid reducer)

Purpose
Acid reducer

Use

- relief frequent heartburn (occurs 2 or more days a week)
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings

Allergy alert: Do not use if you are allergic to lansoprazole.

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.

Ask a doctor before use if you have:

- heart disease
- 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
- requent chest pain
- requent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain

Ask a doctor or pharmacist before use if you are taking:

- warfarin (blood-thinning medicine)
- prescription antifungal or anti-yeast medicines
- diphen (heart medicine)

MADE IN
EXP:
LOT:

NOVARTIS

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Pharmaceuticals North America, Inc. and is used under license.



3 0067-6286-42 6

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DRUG FACTS TEXT	
TYPE/STRENGTH	
DRUG FACTS TITLE	9.0 pt. / Hehhehha Condensed Bold Obl.
HEAD NMS	8.0 pt. / Hehhehha Condensed Bold Obl.
SUBHEADS	6.0 pt. / Hehhehha Condensed Bold
BODY TEXT	6.0 pt. / Hehhehha Condensed
BULLETS	5.0 pt. / Hehhehha Condensed
TRACKING 0	HORIZONTAL SCALE 85% LEADING: 6.5 pt.
CHARACTERSPITCH	<39
BARLINES, MARLINES	1.5 pt., 0.5 pt.

FDA SUBMISSION - Prevacid 42ct Carton (Humacao)

PREVACID[®] 24HR
 Lansoprazole delayed-release capsules 15 mg / acid reducer

42 CAPSULES
 THREE 14-DAY COURSES OF TREATMENT

BONUS 14 FREE capsules!
 (42 capsules for the price of 28)

Actual Size
 ONE 14-DAY COURSE OF TREATMENT

3 BOTTLES INSIDE
42 CAPSULES TOTAL

NDC 0067-6286-29

Sodium Free

Drug Facts

Active ingredient (in each capsule)
 Lansoprazole 15 mg / acid reducer

Use

- treats frequent heartburn (occurs 2 or more days a week)
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings

Allergy alert: Do not use if you are allergic to lansoprazole

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.

Ask a doctor before use if you have

- liver disease
- 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

Ask a doctor or pharmacist before use if you are taking

- warfarin (blood-thinning medicine)
- prescription antifungal or anti-yeast medicines
- digoxin (heart medicine)

Drug Facts (continued)

Other information

- read the directions, warnings and package insert before use
- keep the carton and package insert. They contain important information.
- store at 20-25°C (68-77°F)
- keep product out of high heat and humidity
- protect product from moisture

Inactive ingredients: colloidal silicon dioxide, D&C red No. 28, FD&C blue No. 1, FD&C green No. 3, FD&C red No. 40, gelatin, hydroxypropyl cellulose, low substituted methacrylic acid copolymer, polyethylene glycol, polyacrylate 90, starch, sucrose, sugar sphere, talc, titanium dioxide

Questions or comments?
 1-800-432-0061

Visit us at www.prevacid24hr.com

KEEP THE CARTON AND PACK AGE INSERT. THEY CONTAIN IMPORTANT INFORMATION.

TAMPER-EVIDENT BOTTLE

DO NOT USE: WHEN PAIL SEAL IMPRINTED WITH THIS LOGO IS BROKEN OR MISSING OR BLACK RING AROUND THE CENTER OF EACH CAPSULE IS MISSING OR BLOWN.

DRUG FACTS TEXT	
TYPE/STRENGTH	
DRUG FACTS TITLE	9.0 pt. / Heibelica Condensed Bold Obl.
HEAD NMS	8.0 pt. / Heibelica Condensed Bold Obl.
SUBHEAD	6.0 pt. / Heibelica Condensed Bold
BODY TEXT	6.0 pt. / Heibelica Condensed
BULLETS	5.0 pt. / Heibelica Condensed
TRACKING 0	HORIZONTAL SCALE 85% LEADING: 6.5 pt.
CHARACTERSPUNCH	<39
BARLINES	1.5 pt., 0.5 pt.

FDA SUBMISSION - Prevacid 42ct BONUS Carton (Humacao)



PREVACID[®] 24HR
Lansoprazole delayed-release capsules 15 mg / acid reducer

42 CAPSULES
THREE 14-DAY COURSES OF TREATMENT

Actual Size
ONE 14-DAY COURSE OF TREATMENT

3 BOTTLES INSIDE
42 CAPSULES TOTAL

DAYTONA 500
PROUD SUPPORTER

Sodium Free

Drug Facts

Active ingredient (in each capsule)
Lansoprazole 15 mg

Use

- treats frequent heartburn (occurs 2 or more days a week)
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings

Allergy alert: Do not use if you are allergic to lansoprazole

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.

Ask a doctor before use if you have

- liver disease
- 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

Ask a doctor or pharmacist before use if you are taking

- warfarin (blood-thinning medicine)
- prescription antifungal or anti-yeast medicines
- dipyridin (heart medicine)

Drug Facts (continued)

Other information

- Read the directions, warnings and package insert before use
- Keep the carton and package insert. They contain important information.
- Store at 20-25°C (68-77°F)
- Keep product out of high heat and humidity
- Keep product from moisture

Inactive ingredients: colloidal silicon dioxide, D&C red No. 28, FD&C blue No. 1, FD&C green No. 3, FD&C red No. 40, gelatin, hydroxypropyl cellulose, low substituted hydroxypropyl cellulose, magnesium carbonate, methacrylic acid copolymer, polyethylene glycol, polyacrylate 90, starch, sucrose, sugar sphere, talc, titanium dioxide

Questions or comments?
1-800-432-0061
Visit us at www.pprevacid24hr.com

KEEP THE CARTON AND PACKAGE INSERT. THEY CONTAIN IMPORTANT INFORMATION.

TAMPER-EVIDENT BOTTLE
DO NOT USE IF THE BOTTLE SEAL IS IMPAIRED OR IF THERE IS A CRACK OR OTHER DAMAGE TO THE BLACK BAND AROUND THE CENTER OF EACH CAPSULE IS MISSING OR BROKEN.

Drug Facts (continued)

- theophylline (asthma medicine)
- tacrolimus (immune system medicine)
- atazanavir (medicine for HIV infection)

Stop use and ask a doctor if

- you get diarrhea
- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months

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 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment

- swallow 1 capsule with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 capsule a day
- swallow whole. Do not crush or chew capsules.
- do not use for more than 14 days unless directed by your doctor

Repeated 14-Day Courses (if needed)

- you may repeat a 14-day course every 4 months
- do not take for more than 14 days or more often than every 4 months unless directed by a doctor
- children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.

Drug Facts (continued)

Purpose
Acid reducer

Use

- treats frequent heartburn (occurs 2 or more days a week)
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings

Allergy alert: Do not use if you are allergic to lansoprazole

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.

Ask a doctor before use if you have

- liver disease
- 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

Ask a doctor or pharmacist before use if you are taking

- warfarin (blood-thinning medicine)
- prescription antifungal or anti-yeast medicines
- dipyridin (heart medicine)

Drug Facts (continued)

Other information

- Read the directions, warnings and package insert before use
- Keep the carton and package insert. They contain important information.
- Store at 20-25°C (68-77°F)
- Keep product out of high heat and humidity
- Keep product from moisture

Inactive ingredients: colloidal silicon dioxide, D&C red No. 28, FD&C blue No. 1, FD&C green No. 3, FD&C red No. 40, gelatin, hydroxypropyl cellulose, low substituted hydroxypropyl cellulose, magnesium carbonate, methacrylic acid copolymer, polyethylene glycol, polyacrylate 90, starch, sucrose, sugar sphere, talc, titanium dioxide

Questions or comments?
1-800-432-0061
Visit us at www.pprevacid24hr.com

KEEP THE CARTON AND PACKAGE INSERT. THEY CONTAIN IMPORTANT INFORMATION.

TAMPER-EVIDENT BOTTLE
DO NOT USE IF THE BOTTLE SEAL IS IMPAIRED OR IF THERE IS A CRACK OR OTHER DAMAGE TO THE BLACK BAND AROUND THE CENTER OF EACH CAPSULE IS MISSING OR BROKEN.

DRUG FACTS TEXT	
TYPE/STRENGTH	
DRUG FACTS TITLE	9.0 pt. / Hehhehha Condensed Bold Obl.
HEAD NGS	8.0 pt. / Hehhehha Condensed Bold Obl.
SUBHEADS	6.0 pt. / Hehhehha Condensed Bold
BODY TEXT	6.0 pt. / Hehhehha Condensed
BULLETS	5.0 pt. / Hehhehha Condensed
TRACKING 0	HORIZONTAL SCALE 85% LEADING: 6.5 pt.
CHARACTERSPITCH	<39
BARLINES	MARBLINES: 1.5 pt., 0.5 pt.

FDA SUBMISSION - Prevacid 42ct Carton (Daytona 2012)



PREVACID[®]
Lansoprazole delayed-release capsules 15 mg / acid reducer

• May take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours

• Clinically Proven To Treat Frequent Heartburn

42 CAPSULES
 THREE 14-DAY COURSES OF TREATMENT

Sodium Free

3 BOTTLES INSIDE
42 CAPSULES TOTAL

PREVACID[®]
 Lansoprazole delayed-release capsules 15 mg / acid reducer

Actual Size
 ONE 14-DAY COURSE OF TREATMENT

Drug Facts

Active ingredient (in each capsule)
 Lansoprazole 15 mg / acid reducer

Use

- treats frequent heartburn (occurs 2 or more days a week)
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings

Allergy alert: Do not use if you are allergic to lansoprazole

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.

Ask a doctor before use if you have

- liver disease
- 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

Ask a doctor or pharmacist before use if you are taking

- warfarin (blood-thinning medicine)
- prescription antifungal or anti-yeast medicines
- dipyrone (heart medicine)

Drug Facts (continued)

Other information

- Read the directions, warnings and package insert before use
- Keep the carton and package insert. They contain important information.
- Store at 20-25°C (68-77°F)
- Keep product out of high heat and humidity
- Protect product from moisture

Inactive ingredients: colloidal silicon dioxide, D&C red No. 28, FD&C blue No. 1, FD&C green No. 3, FD&C red No. 40, gelatin, hydroxypropyl cellulose, low substituted hydroxypropyl cellulose, magnesium carbonate, methacrylic acid copolymer, polyethylene glycol, polyacrylate 90, starch, sucrose, sugar spheres, talc, titanium dioxide

Questions or comments?
 1-800-492-0061

Visit us at www.prevacid24hr.com

KEEP THE CARTON AND PACKAGE INSERT. THEY CONTAIN IMPORTANT INFORMATION.

TAMPER-EVIDENT BOTTLE
 DO NOT USE IF THE BOTTLE SEAL IS IMPAIRED OR IF THERE IS A CRACK OR OTHER DAMAGE TO THE BLACK RING AROUND THE CENTER OF EACH CAPSULE IS MISSING OR BROKEN.

Drug Facts (continued)

- theophylline (asthma medicine)
- tacrolimus (immune system medicine)
- atazanavir (medicine for HIV infection)

Stop use and ask a doctor if

- you get diarrhea
- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months

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: 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment

- swallow 1 capsule with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 capsule a day
- swallow whole. Do not crush or chew capsules.
- do not use for more than 14 days unless directed by your doctor

Repeated 14-Day Courses (if needed)

- you may repeat a 14-day course every 4 months
- do not take for more than 14 days or more often than every 4 months unless directed by a doctor
- children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.

Walmart
 Save money. Live better.

If this product is found for sale at a location other than Walmart, please call 1-800-WAL-MART

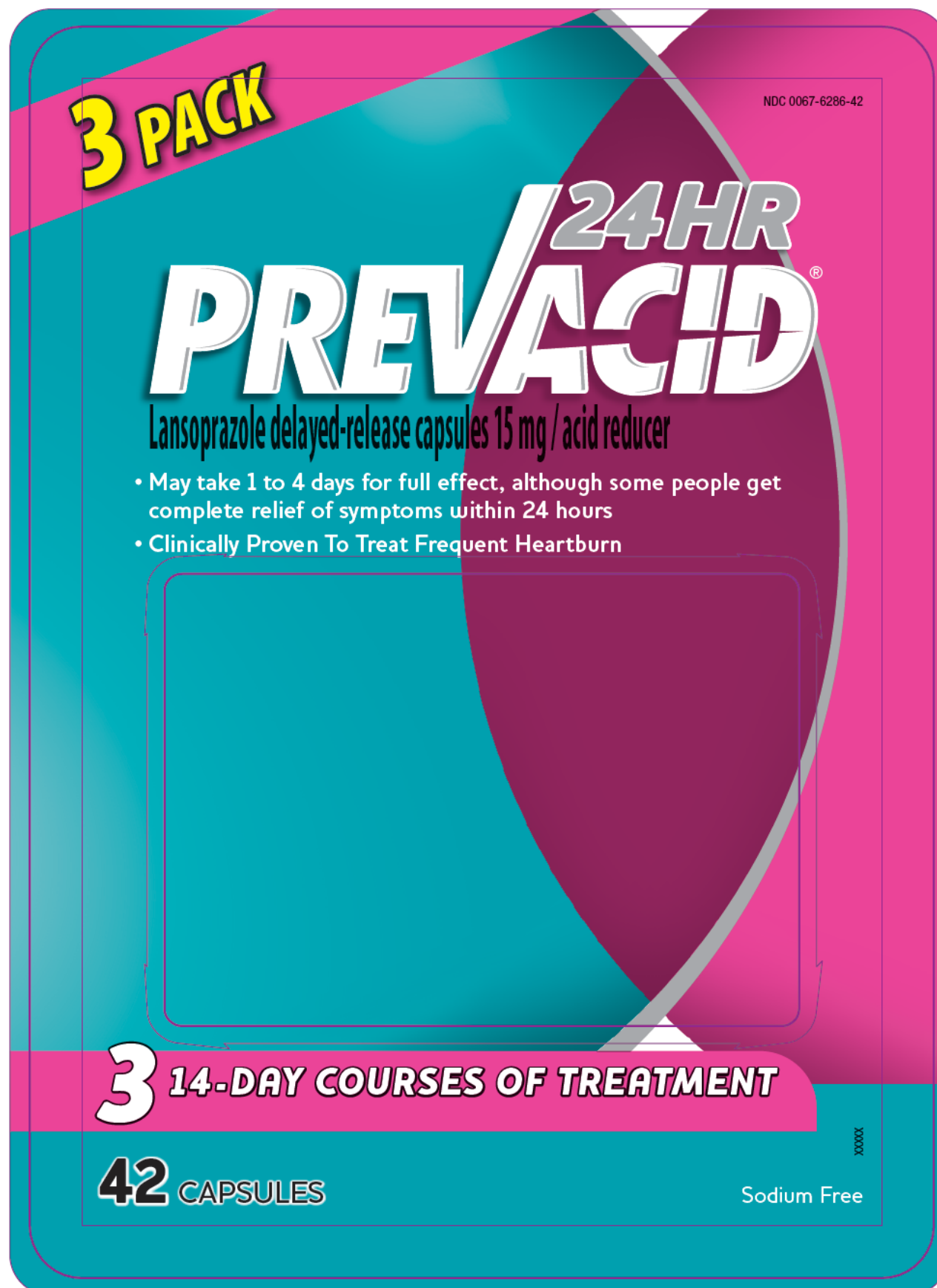
PREVACID[®]
 Lansoprazole delayed-release capsules 15 mg / acid reducer

42 CAPSULES
 THREE 14-DAY COURSES OF TREATMENT

3 BOTTLES INSIDE

DRUG FACTS TEXT	
DRUG FACTS TITLE	TYPE/STRENGTH
HEAD ING	9.0 pt. / Hebelica Condensed Bold Obl.
SUBHEAD	8.0 pt. / Hebelica Condensed Bold Obl.
BODY TEXT	6.0 pt. / Hebelica Condensed Bold
BULLETS	6.0 pt. / Hebelica Condensed
	5.0 pt. / Hebelica Condensed
TRACKING 0	HORIZONTAL SCALE 85% LEADING: 6.5 pt.
CHARACTERSPW: <39	
BAR LINES: 1.5 pt., 0.5 pt.	

FDA SUBMISSION - Prevacid 42ct Walmart Carton (Humacao)



FDA SUBMISSION - Prevacid 42ct Club Pack Front

TAMPER-EVIDENT BOTTLE.
DO NOT USE IF INNER FOIL SEAL IMPRINTED WITH "SEALED FOR YOUR PROTECTION" OR BLACK BAND AROUND THE CENTER OF EACH CAPSULE IS MISSING OR BROKEN.

Drug Facts		Drug Facts (continued)
Active ingredient (in each capsule) Lansoprazole 15 mg	Purpose Acid reducer	
Use • treats frequent heartburn (occurs 2 or more days a week) • not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect		Directions • adults 18 years of age and older • this product is to be used once a day (every 24 hours), every day for 14 days • it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours 14-Day Course of Treatment • swallow 1 capsule with a glass of water before eating in the morning • take every day for 14 days • do not take more than 1 capsule a day • swallow whole. Do not crush or chew capsules. • do not use for more than 14 days unless directed by your doctor Repeated 14-Day Courses (if needed) • you may repeat a 14-day course every 4 months • do not take for more than 14 days or more often than every 4 months unless directed by a doctor • children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.
Warnings Allergy alert: Do not use if you are allergic to lansoprazole 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. Ask a doctor before use if you have • liver disease • 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 Ask a doctor or pharmacist before use if you are taking • warfarin (blood-thinning medicine) • prescription antifungal or anti-yeast medicines • digoxin (heart medicine) • theophylline (asthma medicine) • tacrolimus (immune system medicine) • atazanavir (medicine for HIV infection) Stop use and ask a doctor if • you get diarrhea • your heartburn continues or worsens • you need to take this product for more than 14 days • you need to take more than 1 course of treatment every 4 months 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.		
Visit us at www.prevacid24hr.com		Other information • read the directions, warnings and all information before use • keep the package. It contains important information. • store at 20-25°C (68-77°F) • keep product out of high heat and humidity • protect product from moisture Inactive ingredients colloidal silicon dioxide, D&C red No. 28, FD&C blue No. 1, FD&C green No. 3, FD&C red No. 40, gelatin, hydroxypropyl cellulose, low substituted hydroxypropyl cellulose, magnesium carbonate, methacrylic acid copolymer, polyethylene glycol, polysorbate 80, starch, sucrose, sugar sphere, talc, titanium dioxide Questions or comments? 1-800-452-0051



What you should know about PREVACID®24HR
Please read all information before taking PREVACID®24HR.
Save for future reference.

How PREVACID®24HR Treats Your Frequent Heartburn
PREVACID®24HR stops acid production at the source – the pumps that release acid into the stomach. PREVACID®24HR is taken once a day (every 24 hours), every day for 14 days.

What You Can Expect When Taking PREVACID®24HR
Frequent heartburn can occur anytime during the 24-hour period (day or night). Take PREVACID®24HR in the morning before eating. PREVACID®24HR is clinically proven to treat frequent heartburn. Although some people get complete relief of symptoms within 24 hours, it may take 1 to 4 days for full effect. Make sure you take PREVACID®24HR every day for 14 days to treat your frequent heartburn.

Who Should Take PREVACID®24HR
Adults (18 years and older) with frequent heartburn – when you have heartburn 2 or more days a week.

Who Should NOT Take PREVACID®24HR
People who have one episode of heartburn a week or less, or who want immediate relief of heartburn.

How to Take PREVACID®24HR
14-DAY Course of Treatment
• Swallow 1 capsule with a glass of water before eating in the morning.
• Take every day for 14 days.
• Do not take more than 1 capsule a day.
• Swallow whole. Do not crush or chew capsules.
• Do not use for more than 14 days unless directed by your doctor.

When to Take PREVACID®24HR Again
You may repeat a 14-day course of therapy every 4 months.

When to Talk to Your Doctor
Do not take for more than 14 days or more often than every 4 months unless directed by a doctor.

Warnings and When to Ask Your Doctor
Allergy alert: Do not use if you are allergic to lansoprazole
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.
Ask a doctor before use if you have
• liver disease
• 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
Ask a doctor or pharmacist before use if you are taking
• warfarin (blood-thinning medicine)
• prescription antifungal or anti-yeast medicines
• digoxin (heart medicine)
• theophylline (asthma medicine)
• tacrolimus (immune system medicine)
• atazanavir (medicine for HIV infection)
Stop use and ask a doctor if
• you get diarrhea
• your heartburn continues or worsens
• you need to take this product for more than 14 days
• you need to take more than 1 course of treatment every 4 months
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.

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

Clinical studies prove PREVACID®24HR effectively treats frequent heartburn
In three clinical studies, PREVACID®24HR was shown to be significantly better than placebo in treating frequent heartburn.

How PREVACID®24HR is Sold
PREVACID®24HR is available in 14 capsule, 28 capsule and 42 capsule sizes. These sizes contain one, two and three 14-day courses of treatment, respectively. Do not use for more than 14 days in a row unless directed by your doctor. For the 28 count (two 14-day courses) and the 42 count (three 14-day courses), you may repeat a 14-day course every 4 months.


For Questions or Comments About PREVACID®24HR
Call 1-800-452-0051 or visit us at www.prevacid24hr.com

LOT:
EXP:
MADE IN:

NOVARTIS
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PREVACID® is a registered trademark of Takeda Pharmaceuticals North America, Inc., and is used under license.

DRUG FACTS TEXT	
TYPE/SIZE/STYLE	
DRUG FACTS TITLE	9.0 pt. / Helvetica Condensed Bold Obl.
HEADINGS	8.0 pt. / Helvetica Condensed Bold Obl.
SUBHEADS	6.0 pt. / Helvetica Condensed Bold
BODY TEXT	6.0 pt. / Helvetica Condensed
BULLETS	5.0 pt. / Helvetica Condensed
TRACKING: 0	HORIZONTAL SCALE: 95% LEADING: 6.5 pt.
CHARACTERS/INCH: <39	
BARLINES, HARLINES: 1.5 pt., 0.5 pt.	

FDA SUBMISSION - Prevacid 42ct Club Pack



PREVACID[®] 24HR
Lansoprazole delayed-release capsules 15 mg/acid reducer

• May take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours

Please read the entire package insert before taking PREVACID[®] 24HR.
Save for future reference.

How PREVACID[®] 24HR Treats Your Frequent Heartburn
PREVACID[®] 24HR stops acid production at the source – the pumps that release acid into the stomach. PREVACID[®] 24HR is taken once a day (every 24 hours), every day for 14 days.

What You Can Expect When Taking PREVACID[®] 24HR
Frequent heartburn can occur anytime during the 24-hour period (day or night). Take PREVACID[®] 24HR in the morning before eating. PREVACID[®] 24HR is clinically proven to treat frequent heartburn. Although some people get complete relief of symptoms within 24 hours, it may take 1 to 4 days for full effect. Make sure you take PREVACID[®] 24HR every day for 14 days to treat your frequent heartburn.

Who Should Take PREVACID[®] 24HR
Adults (18 years and older) with frequent heartburn – when you have heartburn 2 or more days a week.

Who Should NOT Take PREVACID[®] 24HR
People who have one episode of heartburn a week or less, or who want immediate relief of heartburn.

How to Take PREVACID[®] 24HR

14-DAY Course of Treatment

- Swallow 1 capsule with a glass of water before eating in the morning.
- Take every day for 14 days.
- Do not take more than 1 capsule a day.
- Swallow whole. Do not crush or chew capsules.
- Do not use for more than 14 days unless directed by your doctor.


When to Take PREVACID[®] 24HR Again
You may repeat a 14-day course of therapy every 4 months.

When to Talk to Your Doctor
Do not take for more than 14 days or more often than every 4 months unless directed by a doctor.

Warnings and When to Ask Your Doctor
Allergy alert: Do not use if you are allergic to lansoprazole

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.



Ask a doctor before use if you have

- liver disease
- 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

Ask a doctor or pharmacist before use if you are taking

- warfarin (blood-thinning medicine)
- prescription antifungal or anti-yeast medicines
- digoxin (heart medicine)
- theophylline (asthma medicine)
- tacrolimus (immune system medicine)
- atazanavir (medicine for HIV infection)

Stop use and ask a doctor if

- you get diarrhea
- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months

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.

Tips for Managing Heartburn

- Avoid foods or drinks that are more likely to cause heartburn, such as rich, spicy, fatty and fried foods, chocolate, caffeine, alcohol and even some acidic fruits and vegetables.

• Eat slowly and do not eat big meals.

• Do not eat late at night or just before bedtime.

• Do not lie flat or bend over soon after eating.

• Raise the head of your bed.

• Wear loose-fitting clothing around your stomach.

• If you are overweight, lose weight.

• If you smoke, quit smoking.

Clinical studies prove PREVACID[®] 24HR effectively treats frequent heartburn
In three clinical studies, PREVACID[®] 24HR was shown to be significantly better than placebo in treating frequent heartburn.

How PREVACID[®] 24HR is Sold
PREVACID[®] 24HR is available in 14 capsule, 28 capsule and 42 capsule sizes. These sizes contain one, two and three 14-day courses of treatment, respectively. Do not use for more than 14 days in a row unless directed by your doctor. For the 28 count (two 14-day courses) and the 42 count (three 14-day courses), you may repeat a 14-day course every 4 months.

For Questions or Comments About PREVACID[®] 24HR
Call 1-800-452-0051 or visit us at www.prevacid24hr.com

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INSERT TEXT	
	TYPE SIZE/STYLE
HEADINGS	8.0 pt. / Myriad Pro Bold
SUBHEADS	7.0 pt. / Myriad Pro Bold
BODY TEXT	7.0 pt. / Myriad Pro Regular
TRACKING:	0 HORIZONTAL SCALE: 100% LEADING: 8.5 pt.
CHARACTERS/WICH:	<39
BARLINES, HARLINES:	1.5 pt., 0.5 pt.

FDA SUBMISSION - Prevacid Standard Insert for Cartons

INSERT TEXT	
	TYPE SIZE/STYLE
HEADINGS	7.75 pt. / Myriad Pro Bold
SUBHEADS	7.0 pt. / Myriad Pro Bold
BODY TEXT	7.0 pt. / Myriad Pro Regular
TRACKING:	0 HORIZONTAL SCALE: 100% LEADING: 9.0 pt.
CHARACTERS/INCH:	<39
BAR LINES, HAIR LINES:	1.5 pt., 0.5 pt.



Please read the entire package insert before taking PREVACID®24HR.
Save for future reference.

How PREVACID®24HR Treats Your Frequent Heartburn

PREVACID®24HR stops acid production at the source – the pumps that release acid into the stomach. PREVACID®24HR is taken once a day (every 24 hours), every day for 14 days.

What You Can Expect When Taking PREVACID®24HR

Frequent heartburn can occur anytime during the 24-hour period (day or night). Take PREVACID®24HR in the morning before eating. PREVACID®24HR is clinically proven to treat frequent heartburn. Although some people get complete relief of symptoms within 24 hours, it may take 1 to 4 days for full effect. Make sure you take PREVACID®24HR every day for 14 days to treat your frequent heartburn.

Who Should Take PREVACID®24HR

Adults (18 years and older) with frequent heartburn – when you have heartburn 2 or more days a week.

Who Should NOT Take PREVACID®24HR

People who have one episode of heartburn a week or less, or who want immediate relief of heartburn.

How to Take PREVACID®24HR

14-DAY Course of Treatment

- Swallow 1 capsule with a glass of water before eating in the morning.
- Take every day for 14 days.
- Do not take more than 1 capsule a day.
- Swallow whole. Do not crush or chew capsules.
- Do not use for more than 14 days unless directed by your doctor.

When to Take PREVACID®24HR Again

You may repeat a 14-day course of therapy every 4 months.

When to Talk to Your Doctor

Do not take for more than 14 days or more often than every 4 months unless directed by a doctor.

Warnings and When to Ask Your Doctor

Allergy alert: Do not use if you are allergic to lansoprazole

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.

Ask a doctor before use if you have

- liver disease
- 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

Ask a doctor or pharmacist before use if you are taking

- warfarin (blood-thinning medicine)
- prescription antifungal or anti-yeast medicines
- digoxin (heart medicine)
- theophylline (asthma medicine)
- tacrolimus (immune system medicine)
- atazanavir (medicine for HIV infection)

Stop use and ask a doctor if

- you get diarrhea
- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months

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.

Tips for Managing Heartburn

- Avoid foods or drinks that are more likely to cause heartburn, such as rich, spicy, fatty and fried foods, chocolate, caffeine, alcohol and even some acidic fruits and vegetables.

• Eat slowly and do not eat big meals.

- Do not eat late at night or just before bedtime.
- Do not lie flat or bend over soon after eating.
- Raise the head of your bed.
- Wear loose-fitting clothing around your stomach.
- If you are overweight, lose weight.
- If you smoke, quit smoking.

Clinical studies prove PREVACID®24HR effectively treats frequent heartburn

In three clinical studies, PREVACID®24HR was shown to be significantly better than placebo in treating frequent heartburn.

How PREVACID®24HR is Sold

PREVACID®24HR is available in 14 capsule, 28 capsule and 42 capsule sizes. These sizes contain one, two and three 14-day courses of treatment, respectively. Do not use for more than 14 days in a row unless directed by your doctor. For the 28 count (two 14-day courses) and the 42 count (three 14-day courses), you may repeat a 14-day course every 4 months.

For Questions or Comments About PREVACID®24HR

Call 1-800-452-0051 or visit us at www.prevacid24hr.com

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/s/

JOEL SCHIFFENBAUER
09/19/2012