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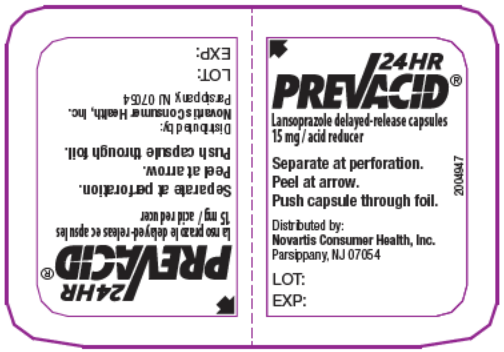
24HR
PREVACID®
Lansoprazole delayed-release capsules
15 mg / acid reducer
Separate at perforation.
Peel at arrow.
Push capsule through foil.
2004847
Distributed by:
Novartis Consumer Health, Inc.
Parsippany, NJ 07054
LOT:
EXP:

LAYOUT Z

Reference ID: 3191440

Drug Facts
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Stroke sizes - 1.25pt & .64pt

ppi
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Leading - 10pt & 7pt

Please read all information before taking PREVACID®24HR.

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 the 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 **light headedness, 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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Drug Facts (continued)

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.

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**

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 **light headedness, 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

SAMPLE – NOT FOR RETAIL SALE.

TREATS FREQUENT HEARTBURN

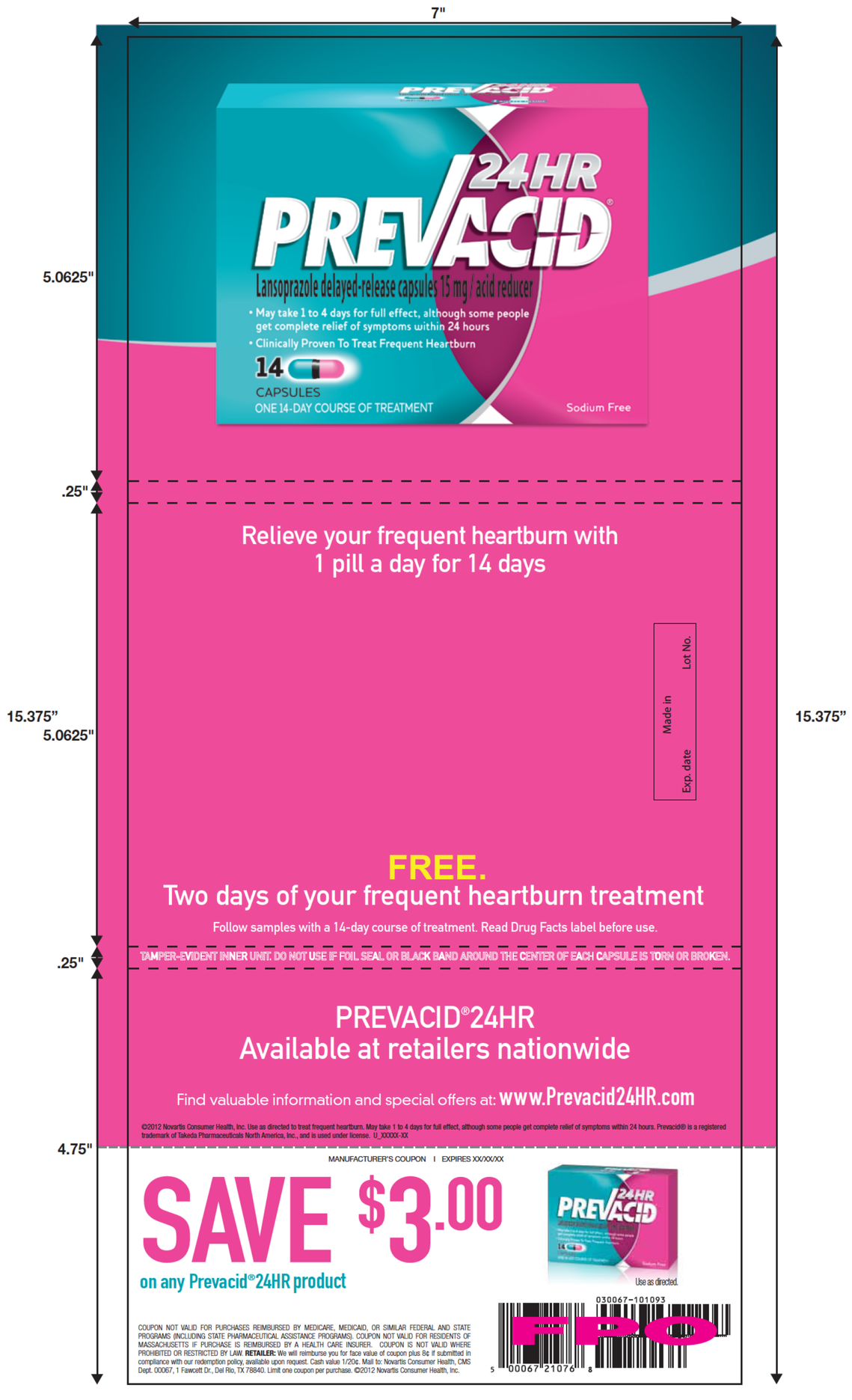
FREE 2 Day Sample And Savings!
Follow samples with a 14-day course of treatment.

2 CAPSULES

7"
5.0625"
.25"
4.75"
.25"
15.375"

DRAFT - FOR FDA APPROVAL

DRAFT - FOR FDA APPROVAL



Reference ID: 3191440

Reference ID: 3191440

DRAFT: FOR FDA REVIEW

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How PREVACID®24HR Treats Your Frequent Heartburn

What You Can Expect When Taking PREVACID®24HR

Who Should Take PREVACID®24HR

Who Should NOT Take PREVACID®24HR

How to Take PREVACID®24HR

Tips for Managing Heartburn

Warnings and When to Ask Your Doctor

Clinical Studies Prove PREVACID®24HR Effectively Treats Frequent Heartburn

How PREVACID®24HR Is Sold

For Questions or Comments About PREVACID®24HR

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Ask a doctor before use if you have

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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)

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.

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Repeated 14-Day Courses (if needed)

- you may repeat a 14-day course every 4 months
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- 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

PROFESSIONAL SAMPLE – NOT FOR RETAIL SALE.

TREATS FREQUENT HEARTBURN

Sodium Free

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

2
CAPSULES

ppi TEXT

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BARLINES, HAIRLINES: 0.0108 in

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CHARACTERS/INCH: <40
BARLINES, HAIRLINES: 0.0069 in., 0.0208 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_XXXXX-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.

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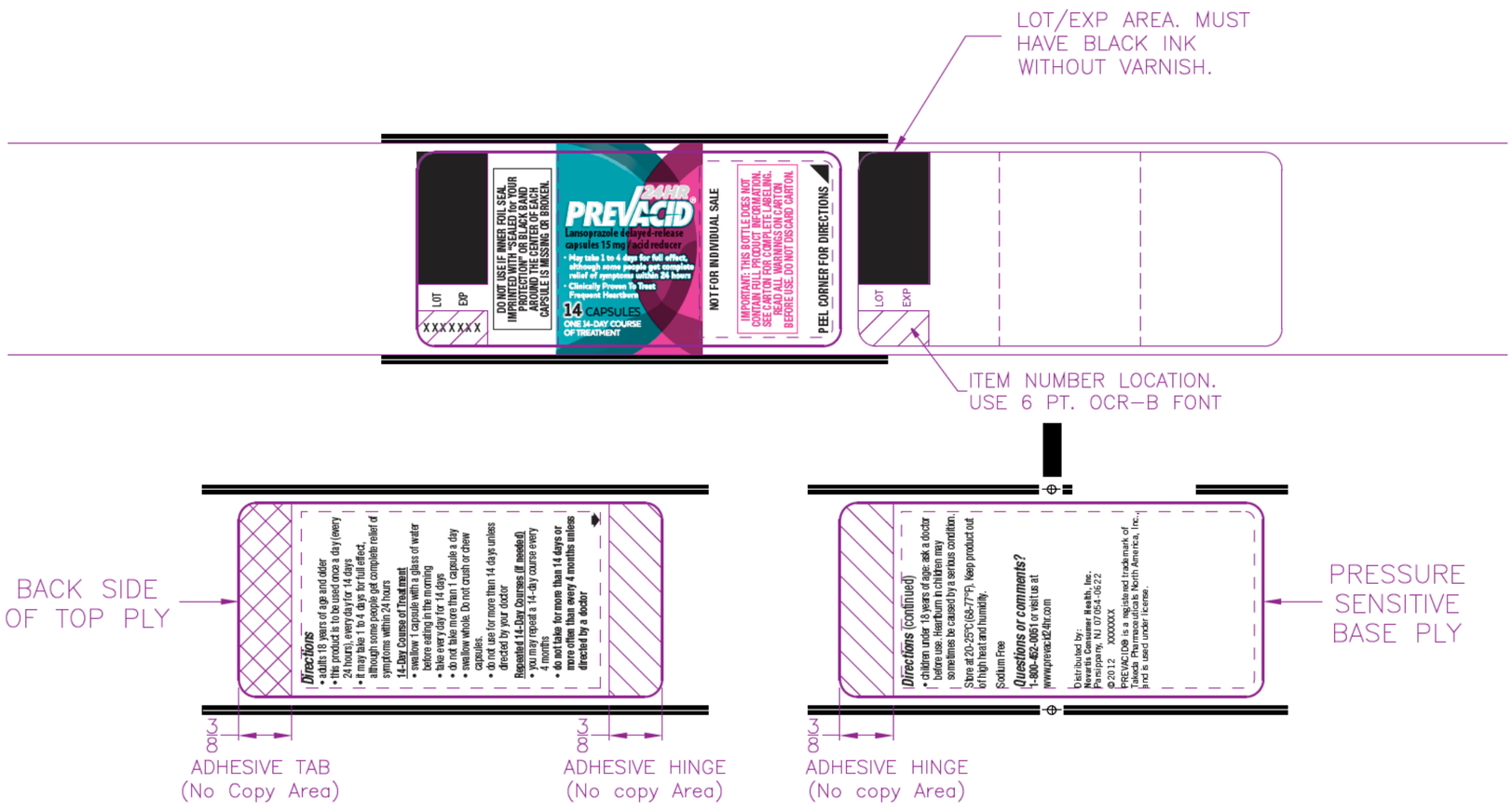
5 00067 21082 9

FDA SUBMISSION - Prevacid 14ct Label (Humacao)



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FDA SUBMISSION - Prevacid 14ct Carton (Humacao)

Reference ID: 3191440

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FDA SUBMISSION - Prevacid 28ct Carton (Humacao)

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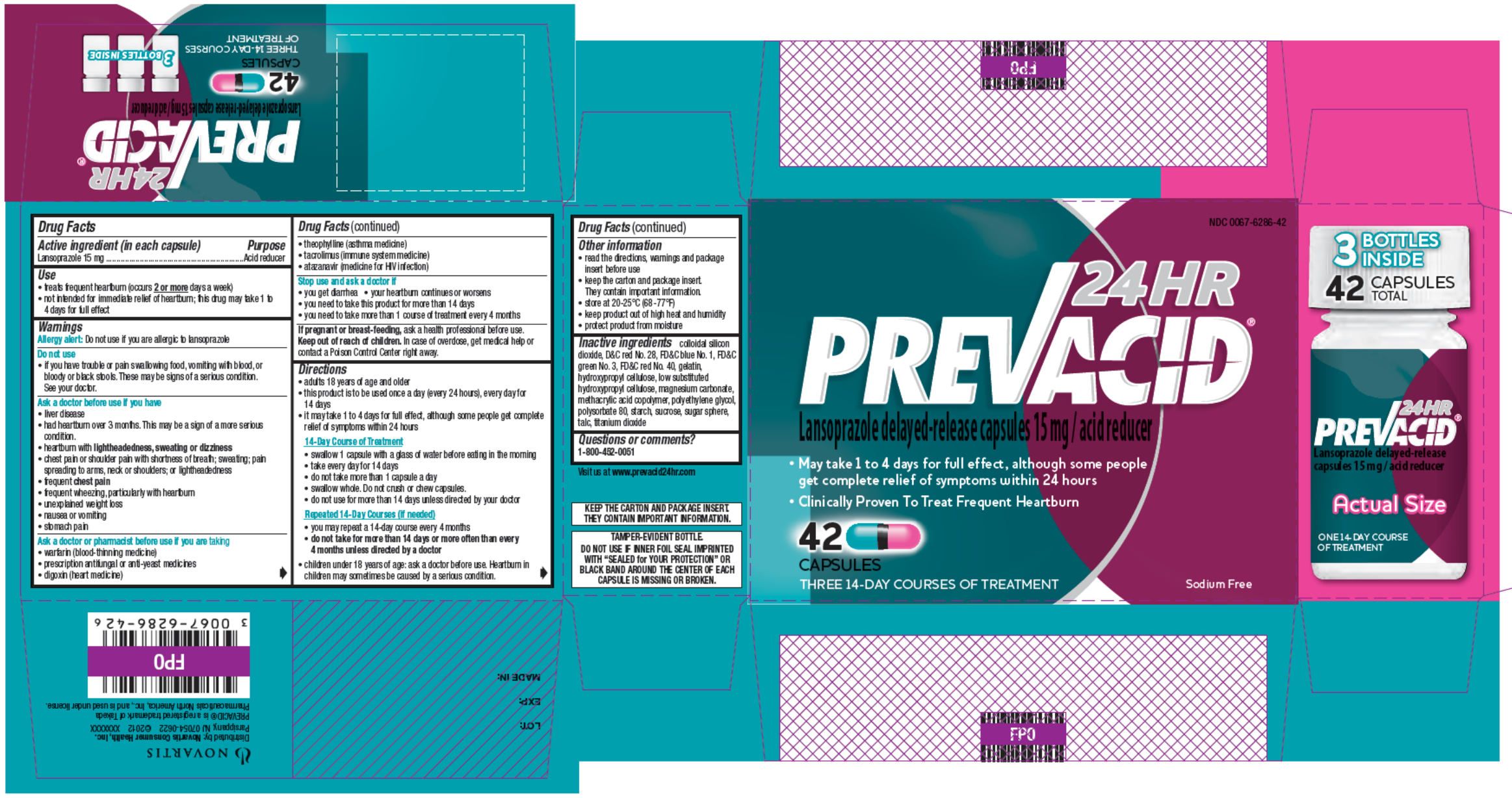

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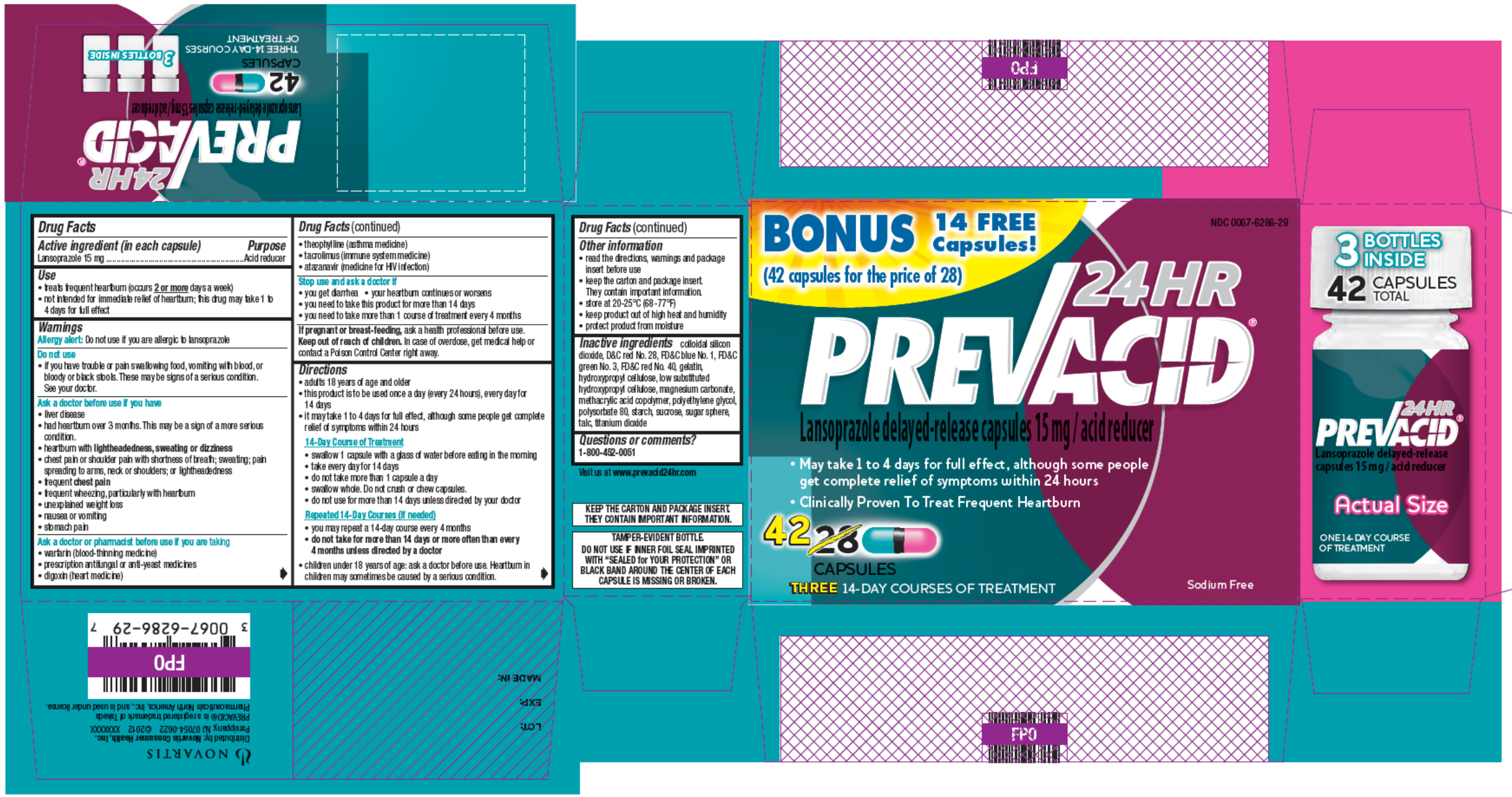
FDA SUBMISSION - Prevacid 42ct Carton (Humacao)

Reference ID: 3191440



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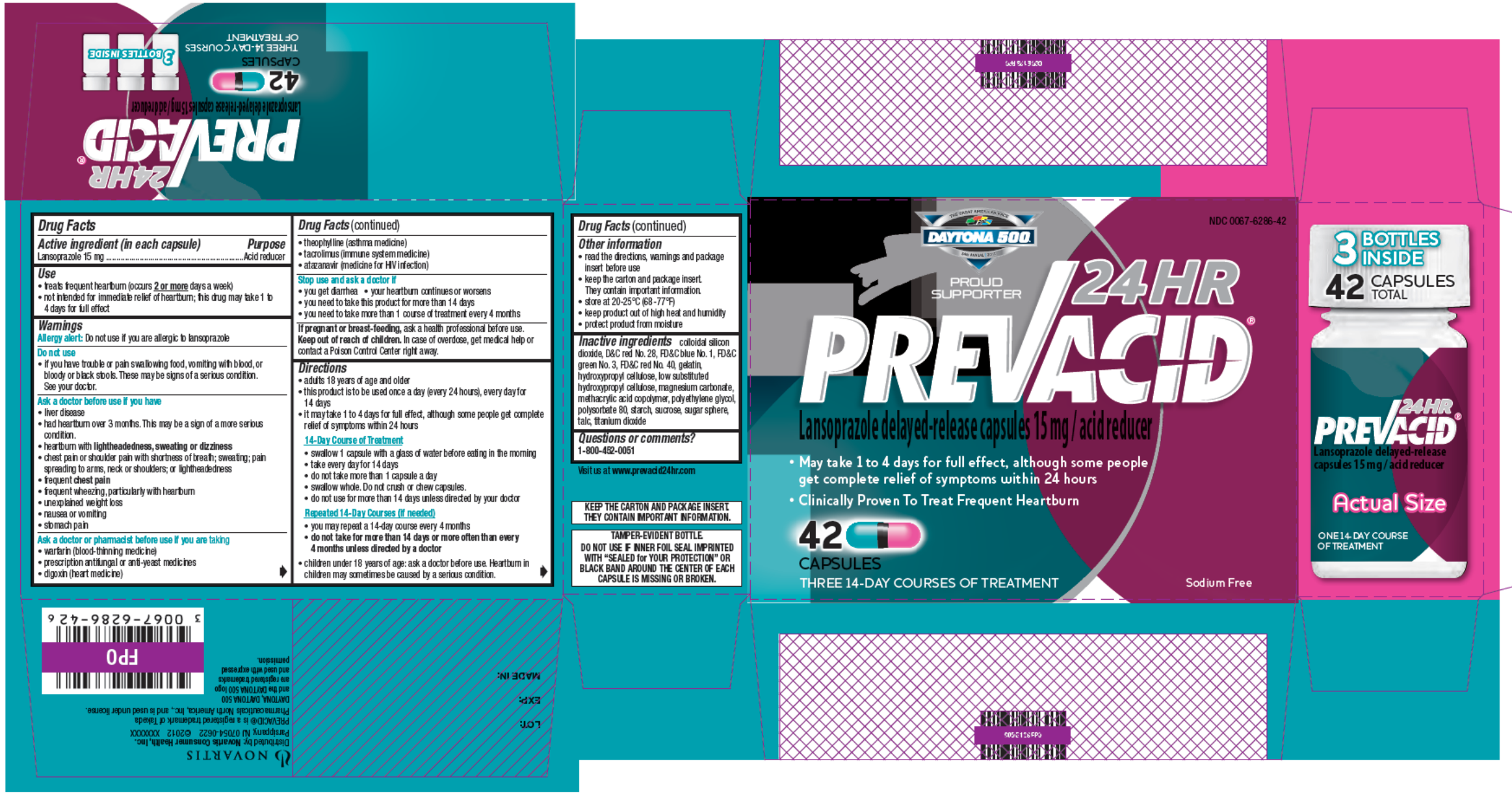

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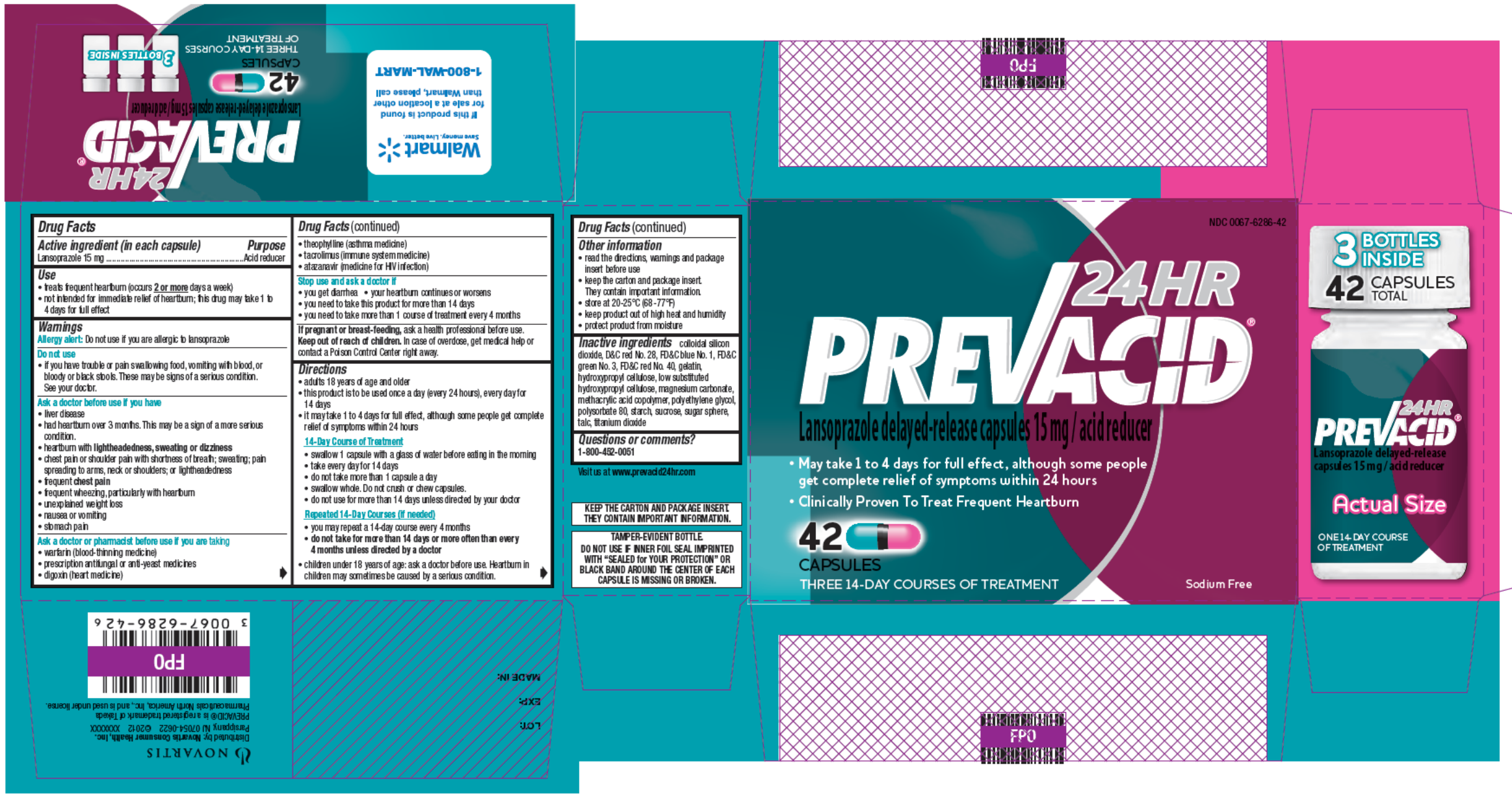
FDA SUBMISSION - Prevacid 42ct Carton (Daytona 2012)

Reference ID: 3191440



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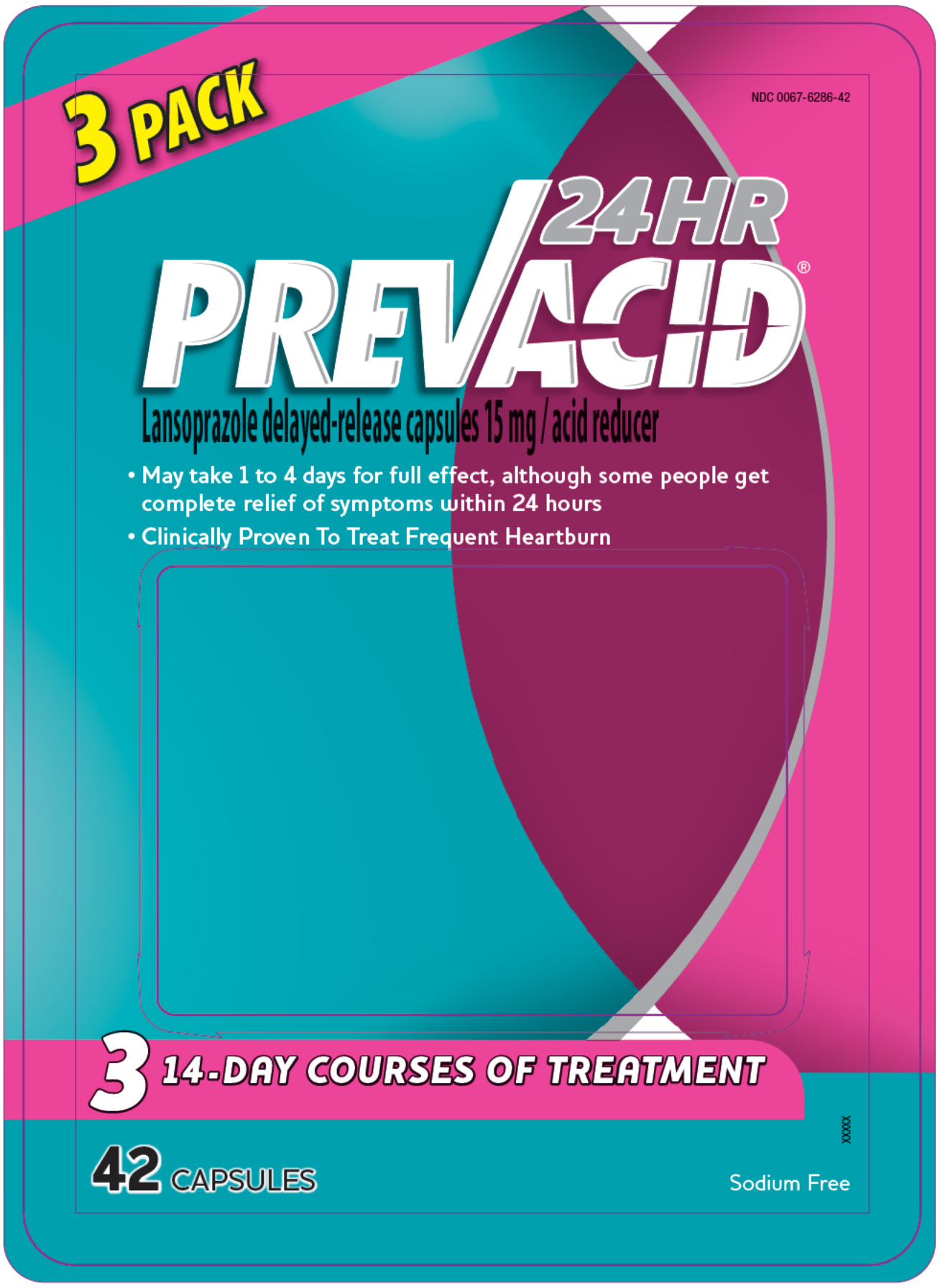
CHARACTERS/INCH: <39	
BARLINES, HAIRLINES: 1.5 pt., 0.5 pt.	

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

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
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Drug Facts (continued)

Directions
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FPO

3 0067-6286-43 3

14-Day Course of Treatment
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- take every day for 14 days
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Repeated 14-Day Courses (if needed)
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Other information
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Questions or comments? 1-800-452-0051

Visit us at www.prevacid24hr.com

What you should know about PREVACID®24HR

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- 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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DRUG FACTS TEXT	
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FDA SUBMISSION - Prevacid 42ct Club Pack

Reference ID: 3191440

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

QUIET ZONE

USE BY MM CODE USE BY DAY

QUIET ZONE

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)
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Stop use and ask a doctor if

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Tips for Managing Heartburn

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FDA SUBMISSION - Prevacid Standard Insert for Cartons

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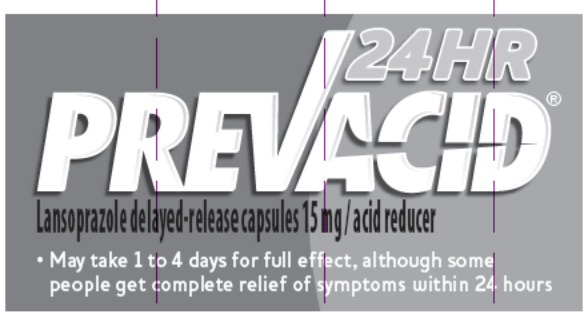
BARLINES, HAIRLINES: 1.5 pt., 0.5 pt.	



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FDA SUBMISSION - Prevacid Insert for Club

Reference ID: 3191440

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JOEL SCHIFFENBAUER
09/19/2012