Draft Labelling for FDA Submission

DRUG FACT FORMATTING: STANDARD		
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BODY TEXT	6 pt.	Helvetica Cond
TRACKING	0	
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LEADING	6.5 pt.	
BARLINES, HAIRLINES	1.5, 0.5 pt.	
CHARACTERS/INCH	<39	
BULLETS	5 pt.	

Reference ID: 4416225

DRUG FACT FORMATTING: STANDARD		
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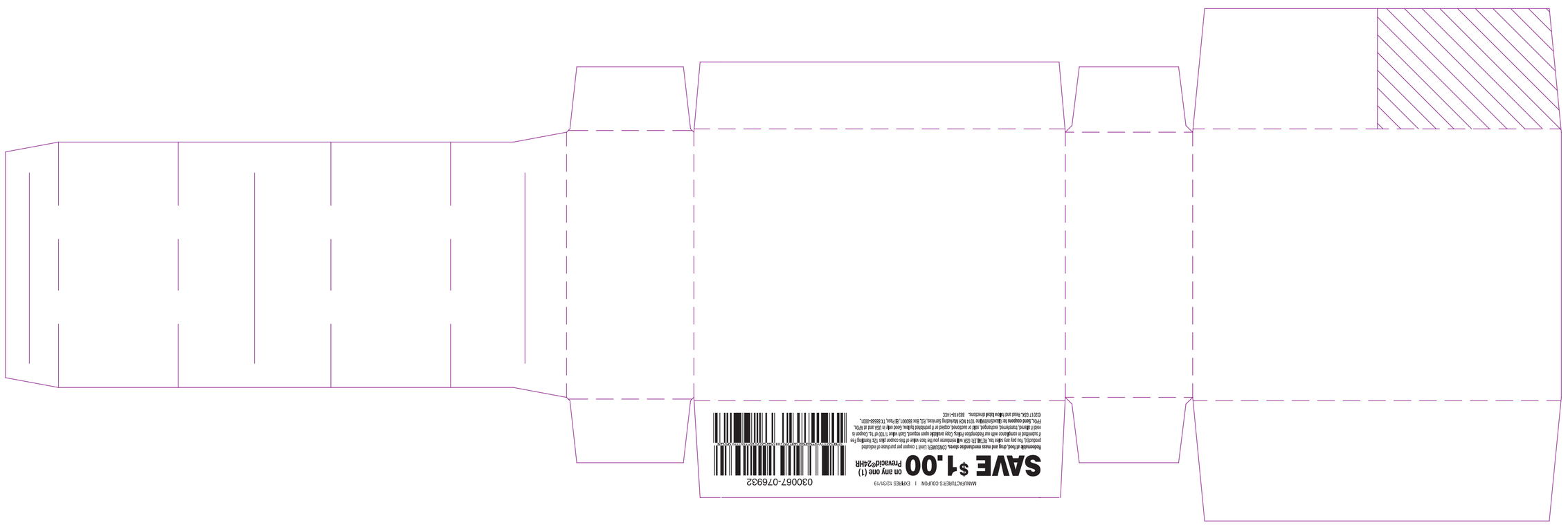

COUPON ART SUPPLIED BY [redacted] (b) (4) - COUPON PRINTED ON INSIDE TOP FLAP OF CARTON

Draft Labelling for FDA Submission

Reference ID: 4416225

Draft Labelling for FDA Submission

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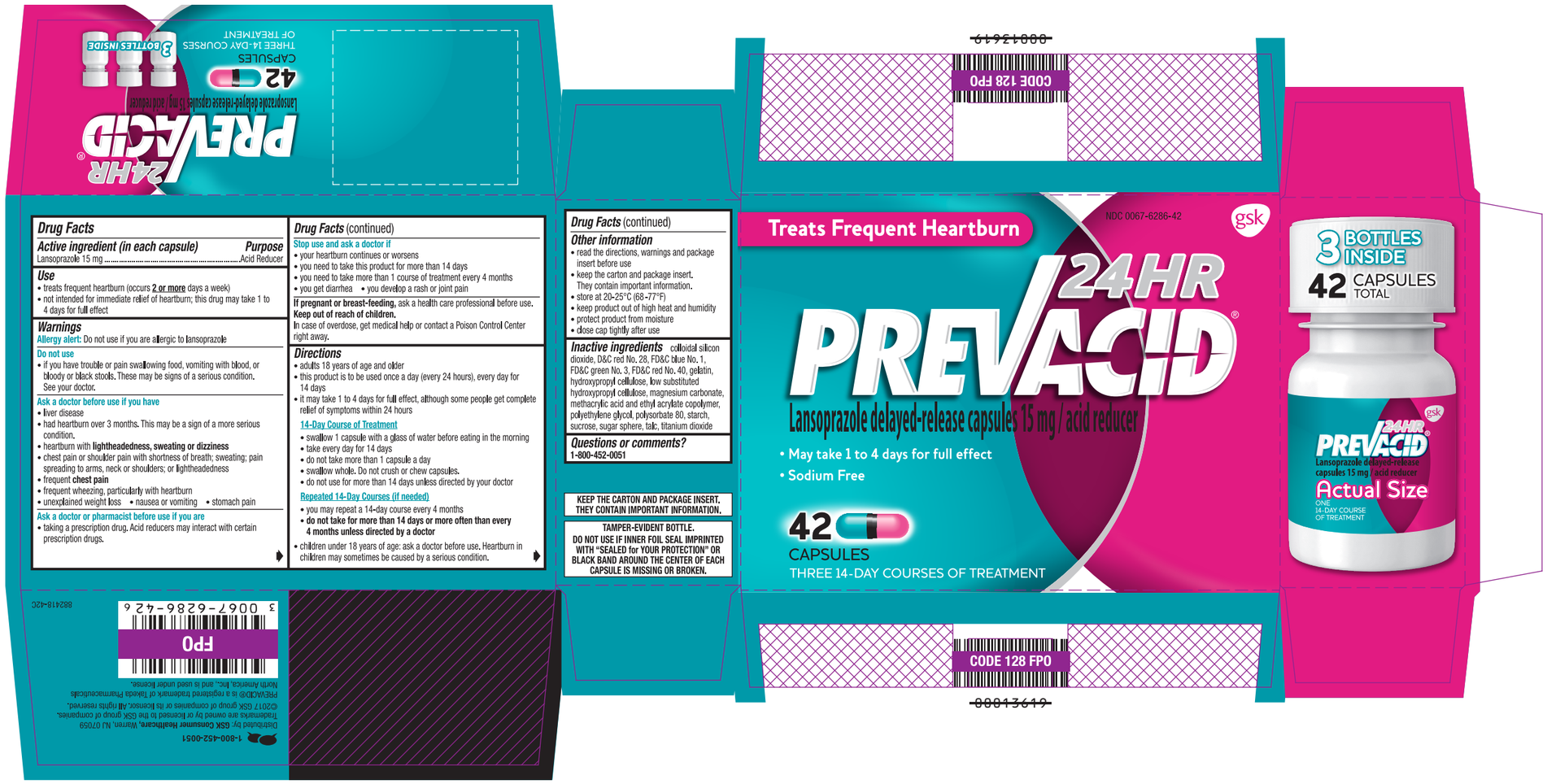

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COUPON ART SUPPLIED BY (b) (4) - COUPON PRINTED ON INSIDE TOP FLAP OF CARTON

Reference ID: 4416225

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
- 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 a prescription drug. Acid reducers may interact with certain prescription drugs.

Stop use and ask a doctor if
- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months
- you get diarrhea
- you develop a rash or joint pain

If pregnant or breast-feeding, ask a health care professional before use.
Keep out of reach of children.
In case of overdose, get medical help or contact a Poison Control Center right away.

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 package insert 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
- close cap tightly after use

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 and ethyl acrylate copolymer, polyethylene glycol, polysorbate 80, starch, sucrose, sugar sphere, talc, titanium dioxide

Questions or comments?
1-800-452-0051

FPO

3 0067-6286-43 3

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**
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Ask a doctor or pharmacist before use if you are
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Stop use and ask a doctor if
- 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
- you get diarrhea
- you develop a rash or joint pain

If pregnant or breast-feeding, ask a health care 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

LOT:
EXP:
MADE IN:

1-800-452-0051

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BARLINES, HAIRLINES	1.5, 0.5 pt.	
CHARACTERS/INCH	<39	
BULLETS	5 pt.	

Draft Labelling for FDA Submission

Treats Frequent Heartburn

gsk

PREVACID® 24HR

Lansoprazole delayed-release capsules 15 mg / acid reducer

- May take 1 to 4 days for full effect
- Sodium Free

QUIET ZONE

128 BAR CODE 6 DIGIT

QUIET ZONE

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

How PREVACID®24HR Treats Your Frequent Heartburn

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What You Can Expect When Taking PREVACID®24HR

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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
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When to Talk to Your Doctor
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Warnings and When to Ask Your Doctor

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

Do not use

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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
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128 BAR CODE 6 DIGIT

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