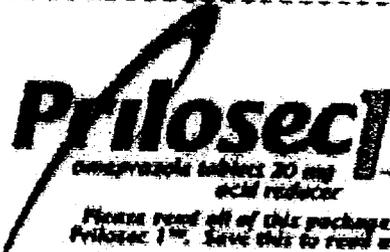


3.1.2 Carton Label

PROPOSED LABEL  
BACK CARTON PANEL

<b>Drug Facts</b>		<b>Drug Facts (continued)</b>	
<b>Active ingredient (in each tablet)</b> <b>Purpose</b> Omeprazole magnesium 20.6 mg ..... Acid reducer (equivalent to 20 mg omeprazole)		<b>Directions</b> Adults 18 years of age and older: <ul style="list-style-type: none"> <li>for prevention of frequent heartburn, swallow 1 tablet with a glass of water in the morning</li> <li>take every day for 14 days</li> <li>do not continue beyond 14 days unless directed by your doctor. If your frequent heartburn continues or returns, it could be a sign of a more serious condition.</li> </ul>	
<b>Uses</b> <ul style="list-style-type: none"> <li>for prevention of the symptoms of frequent heartburn for 24 hours</li> <li>only for those who suffer heartburn two or more days a week</li> </ul>		<ul style="list-style-type: none"> <li>do not take more than 1 tablet a day</li> <li>do not chew or crush the tablets</li> </ul> Children under 18 years of age: ask a doctor	
<b>Warnings</b> <b>Allergy alert</b> Do not use if you are allergic to omeprazole <b>Heartburn Warning.</b> Heartburn can be a sign of a more serious condition. Notify your doctor if you have had heartburn for 3 months or longer without talking to your doctor.			
<b>Do not use</b> <ul style="list-style-type: none"> <li>with other acid reducers</li> </ul>		<b>Other Information</b> <ul style="list-style-type: none"> <li>read the directions, warnings, and package insert before use</li> <li>keep the carton and package insert. They contain important information.</li> <li>store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F)</li> <li>avoid product exposure to excessive heat and humidity</li> <li>protect from moisture</li> </ul>	
<b>Ask a doctor before use if you have</b> <ul style="list-style-type: none"> <li>any of the following symptoms and have not seen a doctor                             <ul style="list-style-type: none"> <li>frequent chest pain</li> <li>chest pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness</li> <li>trouble swallowing food</li> <li>frequent wheezing, particularly with heartburn</li> <li>unexplained weight loss</li> </ul> </li> </ul> These may be signs of more serious conditions. Notify your doctor.			
<b>Ask a doctor or pharmacist before use if you are taking</b> <ul style="list-style-type: none"> <li>warfarin (blood thinning medicine)</li> <li>phenytoin (seizure medicine)</li> <li>ketoconazole (prescription antifungal medicine)</li> </ul>		<b>Inactive ingredients</b> glyceryl monostearate, hydroxypropyl cellulose, hydroxypropyl methyl-cellulose, iron oxide, magnesium stearate, methacrylic acid copolymer, microcrystalline cellulose, paraffin, polyethylene glycol 6000, polysorbate 80, polyvinylpyrrolidone, sodium stearyl fumarate, starch, sucrose, talc, titanium dioxide, triethyl citrate	
<b>Stop use and ask a doctor if</b> <ul style="list-style-type: none"> <li>stomach pain continues or worsens</li> <li>heartburn continues or returns after using this product every day for 14 days</li> </ul> <b>If pregnant or breast-feeding, ask a health professional before use.</b>		Safety Feature-Do not use if tablet blister unit is open or broken.  <b>Questions or comments?</b> Call toll free	
<b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away.		Distributed By Procter & Gamble, Cincinnati, OH 45202	

3.1.3 Package Insert



**Prilosec**  
omeprazole tablets 20 mg  
acid reducer

Please read all of this package insert before taking Prilosec 1™. Save this to read as you need.

**Important Information for Frequent Heartburn Sufferers**

**NEW Prilosec 1** - Don't just treat heartburn, prevent it. Prilosec 1 is a new type of acid-reducing medicine, different from medicines like Pepcid AC\*, Zantac 75\*, Rotalids\* and Tums\*. Prilosec 1 contains omeprazole, the same ingredient in Prilosec\*, the #1 prescription acid medicine in the world. Doctors have prescribed

Prilosec for years to treat acid-related problems in millions of people - and now it is available over the counter in full prescription strength. New Prilosec 1 puts you in control of your frequent heartburn with predictable, daily prevention you can count on.

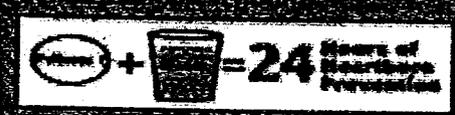
**Who should take Prilosec 1?**

This new acid-reducing medicine is for adults with frequent heartburn. If you are 18 years or older and have heartburn 2 or more days a week, Prilosec 1 is for you.

**How to take Prilosec 1**

- Swallow 1 tablet of Prilosec 1 with a glass of water in the morning. ➤
- Take every day for 14 days. ➤
- Do not continue beyond 14 days unless directed by your doctor. ➤

**The benefit to you**



**Different Medicines for Different Types of Heartburn**

**NEW Prilosec 1** is a new class of medicine now available over the counter.

Unlike other heartburn medications, **NEW Prilosec 1** is specifically for the prevention of the symptoms of frequent heartburn for 24 hours.

\*Registered trademarks of their respective owners and are the property of GlaxoSmithKline Company.

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Continued from previous slide.

Types of Medicine	Antacids (Tums®, Rolaids®)	H2 Blockers (Pepcid AC®, Zantac 75®)	New PRILOSEC 1
	Up to 1 hour 	Up to 8-12 hours 	Up to 24 hours 
	Antacids do not reduce acid production - they only neutralize existing acid.		

**Amount of Time to Onset of Action**

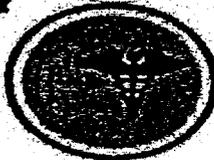
Antacids (Tums®, Rolaids®): Start neutralizing acid within minutes

H2 Blockers (Pepcid AC®, Zantac 75®): Start reducing acid within 1 hour

NEW PriLOSEC 1: Initial acid suppression within 1 hour, peak acid suppression within 3 days of daily dosing

**KEEP YOUR DOCTOR "IN THE LOOP"**

If you have frequent heartburn (2 or more days a week), here are some things to be aware of as you manage your condition:



- Frequent chest pain
- Chest pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- Trouble swallowing food
- Frequent wheezing, particularly with heartburn
- Unexplained weight loss

See back of carton for complete details on warnings.

**During Use**

Do not take PriLOSEC 1 beyond 14 days unless directed by your doctor. If your frequent heartburn continues or returns, it could be a sign of a more serious condition.

Notify your doctor if you have had heartburn for three months or longer without talking to your doctor.

**Stop Use**

Stop use and ask your doctor if your stomach pain continues or worsens or your heartburn returns after using PriLOSEC 1 every day for 14 days.

When in doubt, keep your doctor in the loop. It never hurts to make a phone call to discuss your symptoms - frequent heartburn can be a sign of a more serious condition. Specifically, we recommend contacting your doctor if any of these apply to you:

**Before Use**

Notify your doctor if:

- you are under 18 years old
- you are pregnant or nursing a child
- you are allergic to omeprazole
- you are taking certain prescription medications

Some symptoms can be a sign of a more serious condition. If you have any of the following symptoms and have not seen a doctor, ask a doctor before use:

*Always remember to keep your doctor informed of any frequently occurring heartburn symptoms you may be experiencing.*

**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.

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