

NDA 21-229: Prilosec OTC® ; Item 2 – Revised Labeling For The 2-Count Consumer
Sample Per FDA Letter January 21, 2004 For Approved NDA 21-229
Section II.a – Trial Sample Size Labeling – Consumer

Front Panel of Trial Sample Size Tri-Fold Unit



NDA 21-229: Prilosec OTC® ; Item 2 – Revised Labeling For The 2-Count Consumer
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Middle Panel of Trial Sample Size Tri-Fold Unit

The image shows the middle panel of a trial sample size tri-fold unit for Prilosec OTC. The background is dark purple with a blue dashed border. At the top, the text "FREE STARTER KIT of Prilosec OTC" is written in yellow and white, with a red swoosh underline. Below this, "Treats Frequent Heartburn!" is written in yellow. In the center, there are two identical white rectangular boxes representing the product packaging. Each box contains the following text: "NDC 37000-455-01" at the top, "Treats Frequent Heartburn!" in yellow, the "Prilosec OTC" logo in white and yellow, "omeprazole delayed-release tablet 20 mg / acid reducer" in yellow, and contact information at the bottom: "Call 1-800-759-4841", "Dist. by Procter & Gamble, Cincinnati, OH 45202", "Product of Sweden", "1 TABLET", and "Do not use if pouch is open or torn." To the right of the second box is a barcode. Below the boxes, a white banner contains the text "Please read all of this package insert before taking Prilosec OTC™." At the bottom of the panel, the text "Experience the first couple of days of your 14-day course of treatment!" is written in yellow, followed by "Follow samples with a 14-day course of treatment. Read label on back before use." in white.

FREE STARTER KIT of **Prilosec**
OTC[®]
Treats Frequent Heartburn!

NDC 37000-455-01

Treats Frequent Heartburn!

Prilosec
OTC[™]
omeprazole delayed-release
tablet 20 mg / acid reducer

Call 1-800-759-4841
Dist. by Procter & Gamble, Cincinnati, OH 45202
Product of Sweden

1 TABLET

Do not use if pouch
is open or torn.

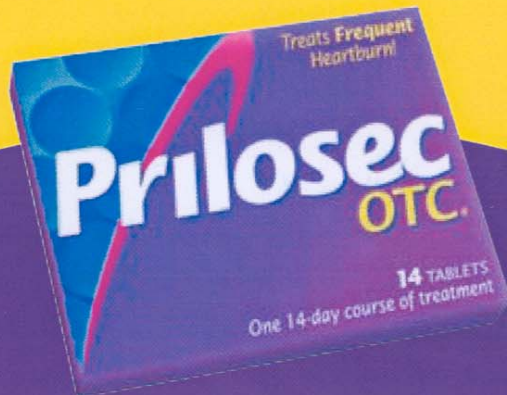
Please read all of this package insert
before taking Prilosec OTC[™].

Experience the first couple of days of your 14-day course of treatment!
Follow samples with a 14-day course of treatment. Read label on back before use.

NDA 21-229: Prilosec OTC® ; Item 2 – Revised Labeling For The 2-Count Consumer
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Back Panel of Trial Sample Size Tri-Fold Unit

<p>Drug Facts</p> <p>Active ingredient (in each tablet) Purpose</p> <p>Omeprazole magnesium delayed-release tablet 20.6 mg (equivalent to 20 mg omeprazole).....Acid reducer</p>	<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>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>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>Warnings</p> <p>Allergy alert: Do not use if you are allergic to omeprazole</p> <p>Do not use if you have</p> <ul style="list-style-type: none"> ■ trouble or pain swallowing food ■ vomiting with blood ■ bloody or black stools <p>These may be signs of a serious condition. See your doctor.</p>	<p>14-Day Course of Treatment</p> <ul style="list-style-type: none"> ■ swallow 1 tablet with a glass of water before eating in the morning ■ take every day for 14 days ■ do not take more than 1 tablet a day ■ do not chew or crush the tablets ■ do not crush tablets in food ■ do not use for more than 14 days unless directed by your doctor
<p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> ■ 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>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 ■ children under 18 years of age: ask a doctor
<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 ■ diazepam (anxiety medicine) ■ digoxin (heart medicine) 	<p>Other information</p> <ul style="list-style-type: none"> ■ 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
<p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ 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>Inactive ingredients glyceryl monostearate, hydroxypropyl cellulose, hypromellose, 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</p> <p>Questions? 1-800-759-4841</p>
<p>Product of Sweden Dist. by Procter & Gamble, Cincinnati, OH 45202</p>	



Flap Folds
Down

**THE POWER IS
IN YOUR HANDS.**

FREE STARTER KIT of **Prilosec OTC.**
Treats Frequent Heartburn!



Sample

Experience the first couple of days of your 14-day course of treatment!
Follow samples with a 14-day course of treatment. Read label on back before use.

Prilosec OTC.
**IT TREATS
FREQUENT HEARTBURN.**

**As A Frequent Heartburn Sufferer, You Can Purchase Prilosec OTC
OVER-THE-COUNTER!**

- Prilosec OTC is to be used once a day (every 24 hours), every day for 14 days.
- Please read drug facts on the back of this card before using.
- For more information call 1-800-759-4841.

Educational
Information
Flap Folds
Up

TREATS FREQUENT HEARTBURN*

- Prilosec OTC is to be used once a day (every 24 hours), every day for 14 days
- Please read Drug Facts label before trying
- For more information call 1-800-759-4841

* Heartburn 2 or more days a week.

<p>Product of Sweden Dist. by Procter & Gamble, Cincinnati, OH 45202</p> <p>Questions? 1-800-759-4841</p>	
<p>Stop and ask a doctor if</p> <ul style="list-style-type: none"> • you need to take more than 1 course of treatment every 4 months • you need to take this product for more than 14 days • your heartburn continues or worsens • you experience any of the following symptoms: <ul style="list-style-type: none"> • dizziness (lightheadedness) • drowsiness (sleepiness) • fainting (loss of consciousness) • headache • heartburn (burning in the stomach) • indigestion (upset stomach) • nausea or vomiting • pain spreading to arms, neck or shoulders; or lightheadedness • chest pain or shoulder pain with shortness of breath; sweating • heartburn with lightheadedness, sweating or dizziness 	<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 • diazepam (anxiety medicine) • digoxin (heart medicine)
<p>Other Information</p> <ul style="list-style-type: none"> • children under 18 years of age: ask a doctor • months unless directed by a doctor • do not take for more than 14 days or more often than every 4 days • you may repeat a 14-day course every 4 months • Repeated 14-Day Courses (if needed) • do not use for more than 14 days unless directed by your doctor • do not crush tablets in food • do not chew or crush the tablets • do not take more than 1 tablet a day • take every day for 14 days • swallow 1 tablet with a glass of water before eating in the morning 	<p>Do not use if you have</p> <ul style="list-style-type: none"> • had heartburn over 3 months. This may be a sign of a more serious condition. • these may be signs of a serious condition. See your doctor. • bloody or black stools • vomiting with blood • trouble or pain swallowing food <p>Do not use if you have</p> <ul style="list-style-type: none"> • an allergy to omeprazole <p>Warnings</p> <ul style="list-style-type: none"> • Allergy alert: Do not use if you are allergic to omeprazole
<p>14-Day Course of Treatment</p> <ul style="list-style-type: none"> • complete relief of symptoms within 24 hours • if you take 1 to 4 days for full effect, although some people get • 14 days • this product is to be used once a day (every 24 hours), every day for • adults 18 years of age and older 	<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>Active ingredient (in each tablet)</p> <p>Omeprazole magnesium delayed-release tablet, 20.6 mg (equivalent to 20 mg omeprazole)</p> <p>Purpose</p> <p>Acid reducer</p>
<p>Drug Facts (continued)</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p> <p>If pregnant or breast-feeding: ask a health professional before use.</p>	

READY TO FIGHT FREQUENT HEARTBURN?

SAMPLES INSIDE!

Educational
Information

Back Panel

Sample
Back Panel

Front of
Tri-fold
Unit