

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-229

APPROVED DRAFT LABELING

NDA 21-229: Prilosec OTC™ ; Item 2 – Revised Draft Labeling (16 June 2003)

Appendix 2.6 – Trial Sample Size Labeling

NEW!

FREE STARTER KIT of new **Prilosec OTC**

Treats Frequent Heartburn!

Prilosec OTC
omeprazole delayed release
tablet 20 mg / acid reducer

Prilosec OTC
omeprazole delayed release
tablet 20 mg / acid reducer

TABLET Do not use if pouch is open or torn.

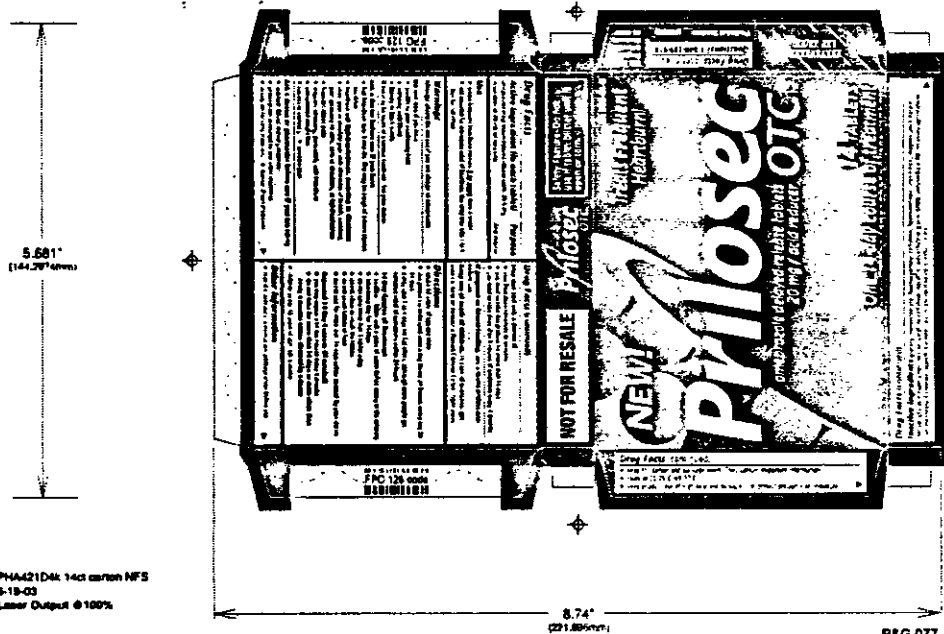
TABLET Do not use if pouch is open or torn.

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 Draft Labeling (16 June 2003)
Appendix 2.6 (Cont'd) – Trial Sample Size Labeling

<p>Drug Facts</p> <p>Active ingredient (in each tablet) Purpose 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 once a day before eating ■ 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>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>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>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 align="right">Product of Sweden</p>	<p>Questions? 1-800-759-4841</p> <p align="right">Dist. by Procter & Gamble, Cincinnati, OH 45202 42431715</p>

14ct Prilosec Inner carton (no Upc)



PH4A21D4k 14ct carton NFS
6-18-03
Laser Output @100%

P&G 077
P&G 137
P&G 054
P&G 055



Blueprint#: HCR01471-01

PRODUCT INFORMATION Product Name: Prilosec OTC Description: 14ct Tablets (For Sale) Manufacturer: Procter & Gamble Company Part No: PH4A21D4k Date: 6-18-03		TECHNICAL AND DIMENSIONAL Drawing No: HCR01471-01 Date: 6-18-03 Author: [Name] Checker: [Name]
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← PRESS DIRECTION
UPC DIRECTION →

THE PROCTER & GAMBLE CO. HEALTH-CARE	
PRODUCT NUMBER HCR01471-01	PART-PRICE NEW
AUTHORIZED BY: JOHNEADICICCO - HCRC - (513)622-3239, 1/27/2003	

1 Shaded area represents code 128 subset C location. Code should be centered in designated area, top to bottom and side to side. Code height to be a minimum of 5/16" tall (8mm), 100% magnification.

2 See material specification for manufacturers glue flap tolerance information.

FINAL ARTWORK APPROVAL		
LIPSON ALPERT GLASS & ASSOCIATES 2100 N. W. 10th St., Suite 100 Ft. Lauderdale, FL 33304		
PROJECT INFORMATION Product: PRILLOSEC Description: 14ct Tablets (For Sale) Part No: PH4A21D4k Date: 6-18-03	STUDIO INFORMATION Job No: PH4A21D4k File No: PH4A21D4k.dwg Studio Contact: [Name] Job Date: [Date]	COMPUTER EQUIVALENTS PMS: 100% CMYK PMS: 100% CMYK PMS: 100% CMYK
PRINTING & FINISHING SPECIFICATIONS Color: [] Ink: [] Paper: [] Finish: []	TECHNICAL AND DIMENSIONAL Size: [] Weight: [] Material: [] Tolerance: []	PRINTING APPROVALS Designer: [Signature] Checker: [Signature] Approver: [Signature]
Approved For Release: [Signature]		

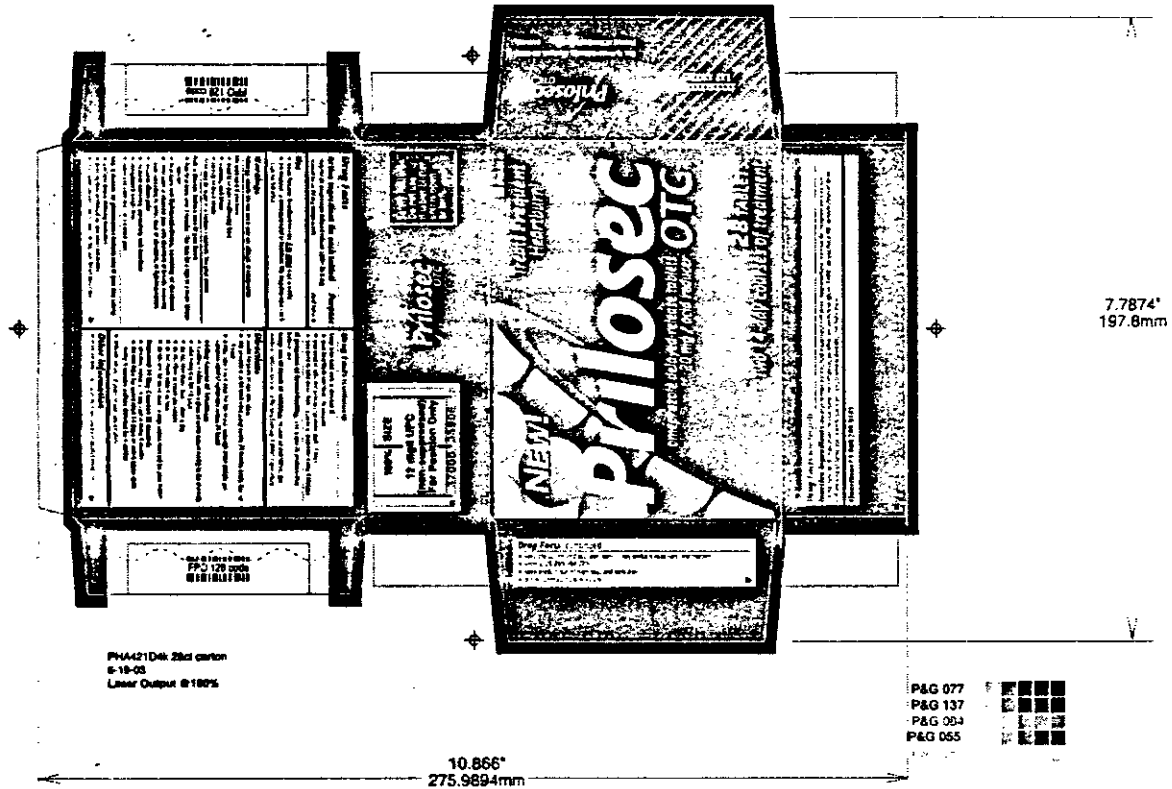


14 ct carton with tab

<p>Drug Facts</p> <p>Active ingredient (in each tablet): Esomeprazole magnesium delayed-release tablet 20 mg equivalent to 20 mg esomeprazole. Purpose: Acid reducer.</p> <p>Use:</p> <ul style="list-style-type: none"> • treats frequent heartburn (up to 14 days a week) • use according to complete relief of heartburn, the only way to take 1 or 4 days for full effect. <p>Warnings:</p> <p>• Allergy alert: Do not use if you are allergic to esomeprazole.</p> <p>Do not use if you have:</p> <ul style="list-style-type: none"> • trouble or pain swallowing food • vomiting with blood • black or dark stools <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: light-headedness, dizziness or dizziness • chest pain or pressure, pain with shortness of breath, sweating, pain spreading to arm, neck or shoulder, or light-headedness • history of stroke • frequent allergic, particularly with heartburn • esophageal reflux (acid) • trouble or vomiting • stomach gas <p>Ask a doctor or pharmacist before use if you are taking:</p> <ul style="list-style-type: none"> • certain blood-thinning medicine • prescription medicine or any other medicine • alcohol, grapefruit juice • digoxin heart medicine 		<p>Drug Facts (continued):</p> <p>See use and ask a doctor if:</p> <ul style="list-style-type: none"> • you experience symptoms of overdose • 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>If pregnant or breast-feeding, ask a health professional before use.</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>Directions:</p> <ul style="list-style-type: none"> • adults 18 years of age and older • use product as to be about once a day every 24 hours, every day for 14 days • take 1 or 4 days for full effect, although some people get immediate relief of symptoms within 24 hours <p>14-Day Course of Treatment:</p> <ul style="list-style-type: none"> • swallow 1 water 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>Repackaged 14-Day Course (if available):</p> <ul style="list-style-type: none"> • use this tablet 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</p> <p>Other information:</p> <ul style="list-style-type: none"> • See the warnings, warnings and package insert before use
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Back

28ct Prilosec Outer Carton (holds two 14ct cartons)



Blueprint#: HCR01440-02

Product Name: Prilosec OTC Description: 28ct Carton Part Number: PH4421D4 Revision: 03		Date: 06/18/03 Author: [Name] Checker: [Name]
Material: [Material] Quantity: [Quantity]	Location: [Location] Status: [Status]	Comments: [Comments]



← PRESS DIRECTION
UPC DIRECTION →

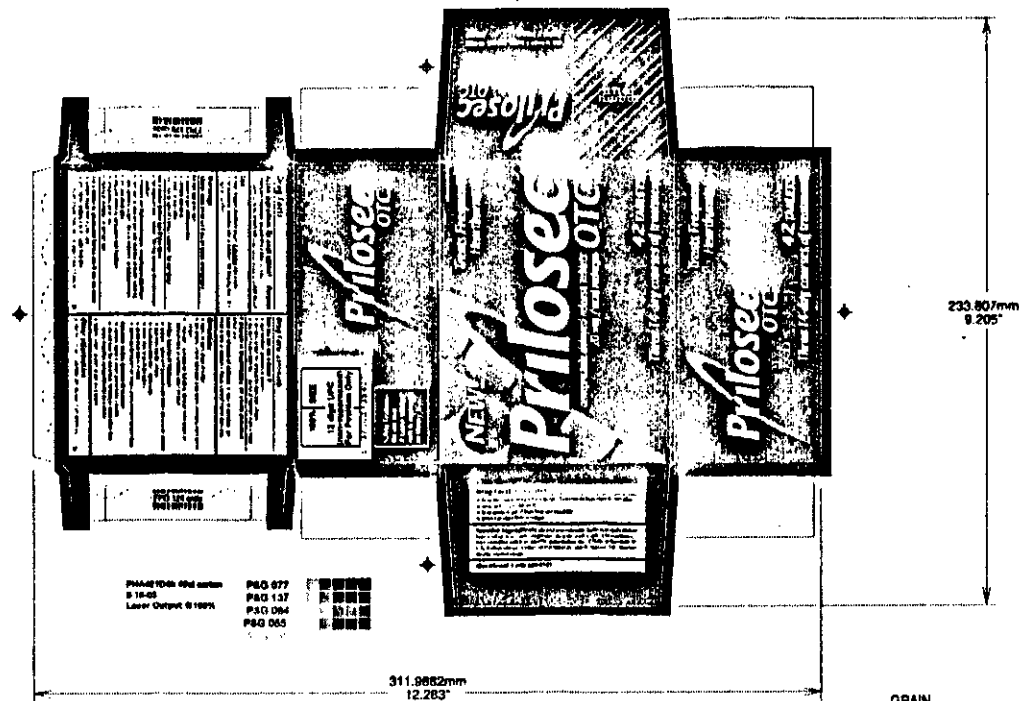
THE PROCTER & GAMBLE CO. HEALTH CARE	
HCR01440-02	HCR01440-01
Authorized for issue by: John Eadecore HCR0-15131622-3239 01/29/2003	

1) Bars represent code Subset C location. Code should be centered on flap top to bottom and side to side. Code height to be minimum 3/16" tall (8mm). 100% Magnification.

2) See material Specification for manufacturers glue flap tolerance information.

FINAL ARTWORK APPROVAL	
LIPSON AIRPORT GLASS & ASSOCIATES Product: PRILLOSEC 28ct Boxes Description / Size: 28ct Date: 06/18/03	COMPUTER EMULATED P&G 077 P&G 137 P&G 054 P&G 055 TENTS / MARK COLORS [Color Swatches]
APPROVED BY: [Signature] DATE: [Date]	LIPSON APPROVALS [Signatures]

42ct Prilosec Outer Carton(holds three 14ct cartons)



Blueprint: NCR01438-02

Product Name	Prilosec OTC
Manufacturer	Procter & Gamble
Lot Number	
Expiration Date	
Barcode	

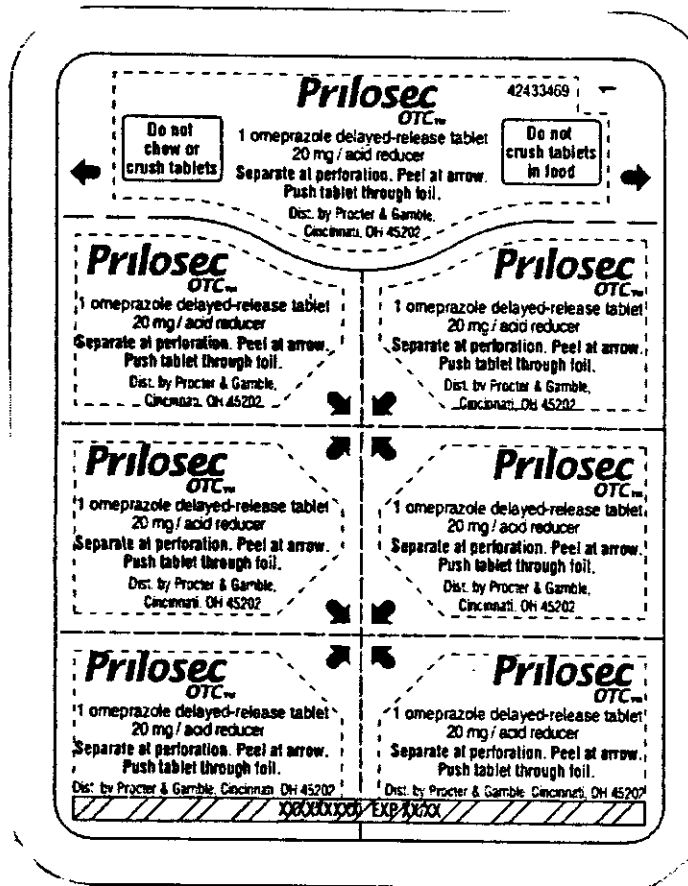
1) Data represent code Subint C location. Code should be centered on flap top to bottom and side to side. Code height to be minimum 5/16" tall (8mm), 100% Magnification.

2) See material Specification for manufacturers glue flap tolerance information.

THE PROCTER & GAMBLE CO. HEALTHCARE	
NCR01438-02	HCW1438-01
Manufactured by: Procter & Gamble John L. Eades is NCR01438-02, 01-2W-001	

FINAL ARTWORK APPROVAL	
LIPSON AIRPORT GLASS & ASSOCIATES	
Project: PRILosec OTC labels Date: 10/15/05 Design: [] Color: [] Material: [] Finish: []	Job No. [] Date of Order [] Date of Delivery [] Date of Payment [] Date of Invoice [] Date of Receipt []
Approved By: [] Date: []	Approved By: [] Date: []

NDA 21-229: PRILOSEC OTC™
Item 2 – Revised Draft Labeling (16 June 2003)
Appendix 2.5
Blister Card Labeling



NDA 21-229: PRILOSEC OTC™

Item 2 – Revised Draft Labeling (16 June 2003)

Appendix 2.3

Configuration of Plastic Overlay for 42-Count Package

