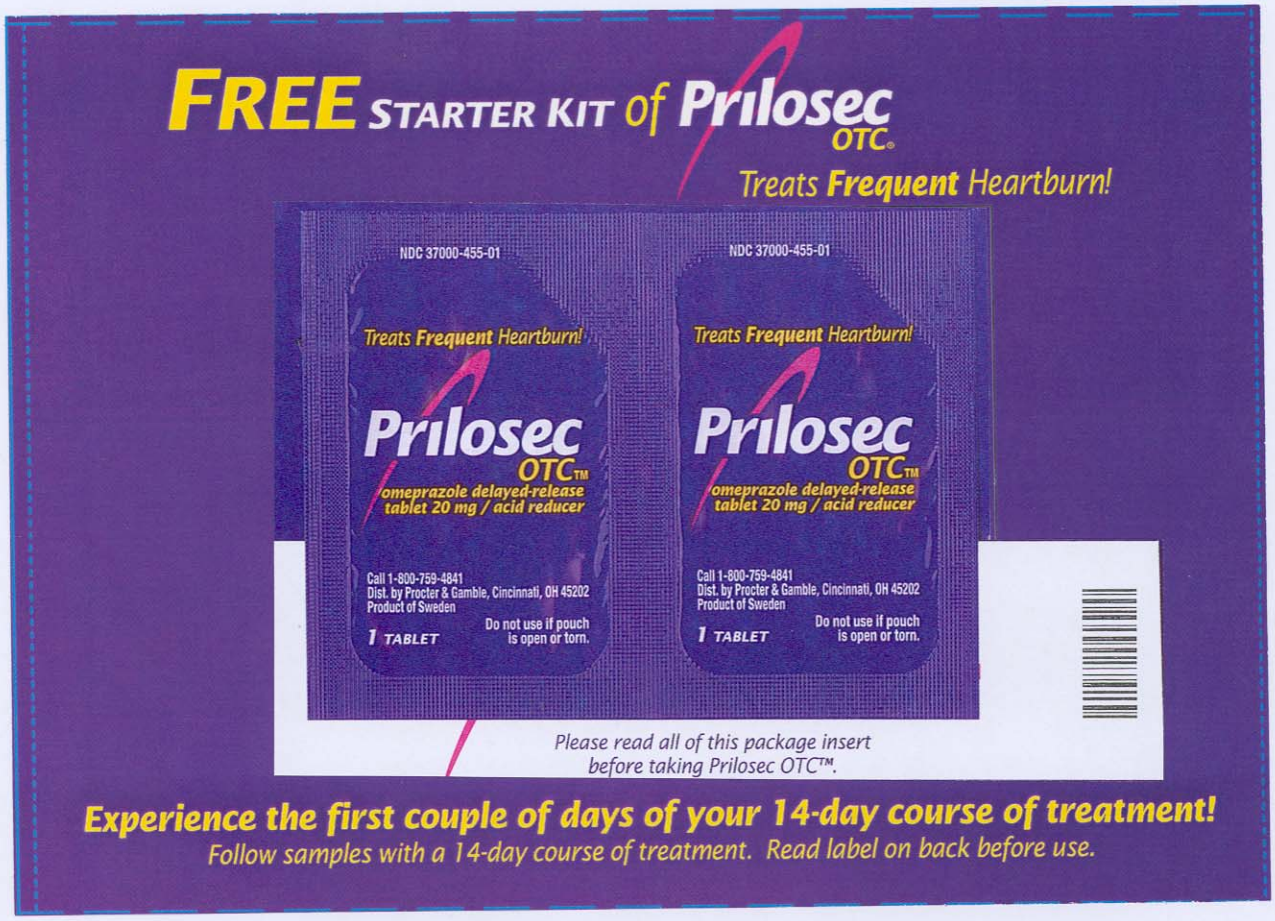
NDA 21-229: Prilosec OTC® ; Item 2 – Revised Labeling For The 2-Count Consumer Sample Per FDA Letter January 21, 2004 For Approved NDA 21-229
Section II.a – Trial Sample Size Labeling – Consumer

Front Panel of Trial Sample Size Tri-Fold Unit

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

Middle Panel of Trial Sample Size Tri-Fold Unit



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

Back Panel of Trial Sample Size Tri-Fold Unit

Drug Facts

Active ingredient (in each tablet) **Purpose**

Omeprazole magnesium delayed-release tablet 20.6 mg (equivalent to 20 mg omeprazole)..... 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 omeprazole

Do not use if you have
- trouble or pain swallowing food
- vomiting with blood
- bloody or black stools

These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have
- 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)
- prescription antifungal or anti-yeast medicines
- diazepam (anxiety medicine)
- digoxin (heart medicine)

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

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 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

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

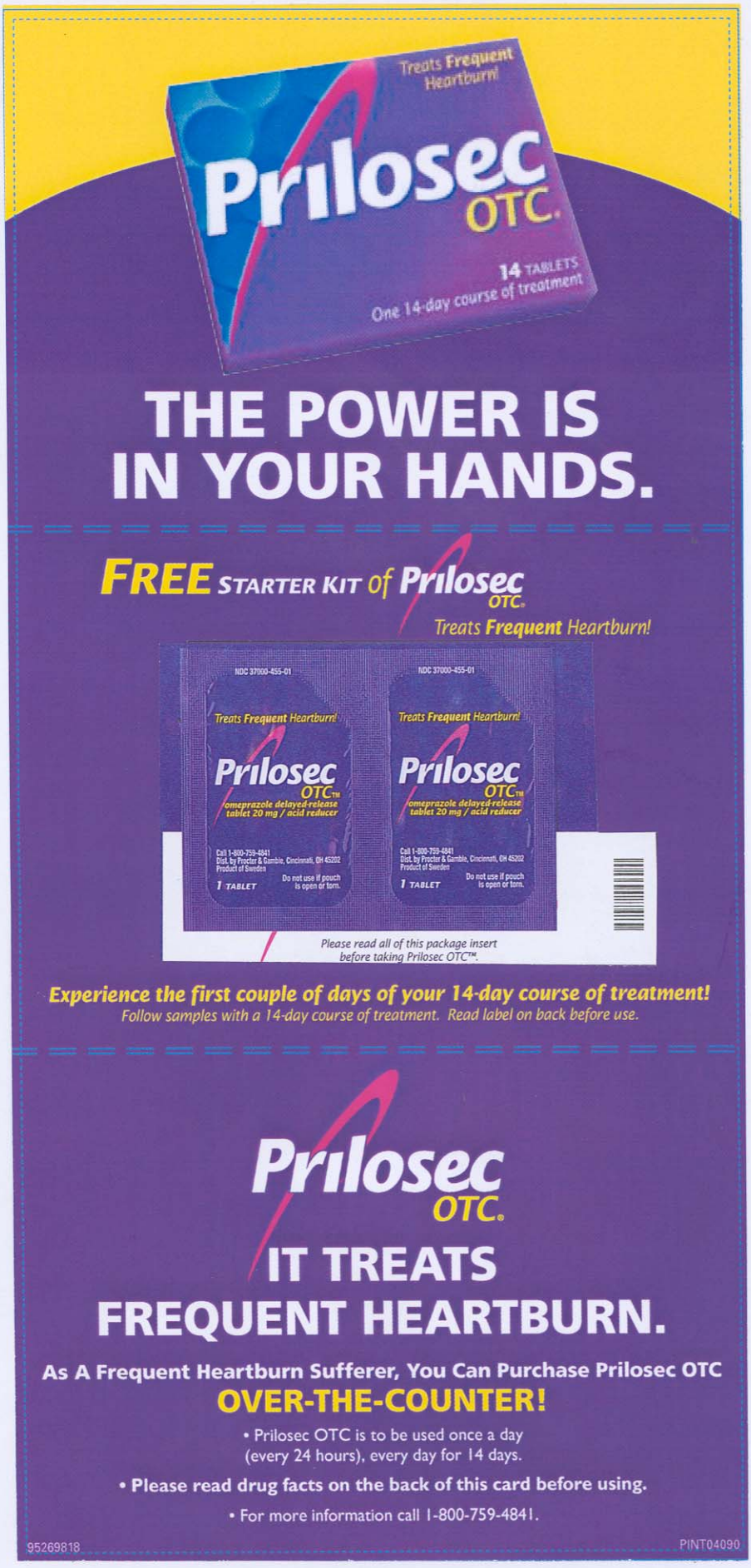
Other information

- 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

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

Questions? **1-800-759-4841**

Product of Sweden Dist. by Procter & Gamble, Cincinnati, OH 45202



Flap Folds Down

Sample

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.

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Warnings

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These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have

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- heartburn with **lightheadedness, sweating or dizziness**
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Drug Facts (continued)

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Questions? 1-800-759-4841

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READY TO FIGHT FREQUENT HEARTBURN?

SAMPLES INSIDE!

Educational Information

Back Panel

Sample Back Panel

Front of Tri-fold Unit