NDA 21-229: Prilosec OTC<sup>TM</sup>; Item 2 – Revised Draft Labeling (16 June 2003) Appendix 2.6 - Trial Sample Size Labeling



Follow samples with a 14-day course of treatment. Read label on back before use.

## NDA 21-229: Prilosec OTC<sup>TM;</sup> Item 2 – Revised Draft Labeling (16 June 2003) Appendix 2.6 (Cont'd) – Trial Sample Size Labeling

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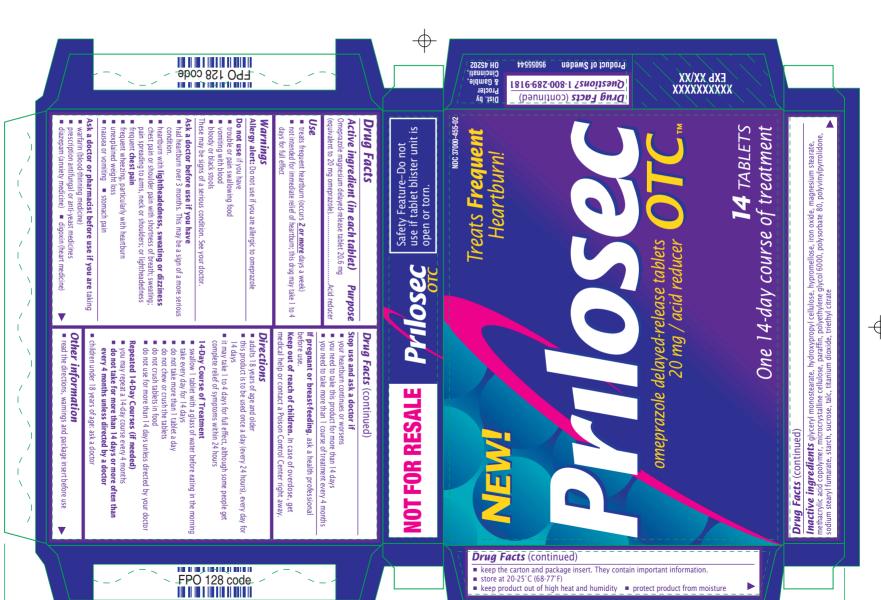
## **14ct Prilosec Carton**



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Inactive ingrealents 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

Drug Facts         Active ingredient (in each tablet) Omeprazole magnesium delayed-release tablet 20.6 mg (equivalent to 20 mg omeprazole)Acid reducer         Use         • treats frequent hearburn (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	Drug Facts (continued) Stop use and ask a doctor if • your hearburn 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 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.
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 over 3 months. This may be a sign of a more serious condition.         • heartburn over 3 months. This may be a sign of 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         • ad obcor or pharmacist before use if you are taking         • warfarin (blood-thinning medicine)	<ul> <li>Directions</li> <li>adults 18 years of age and older</li> <li>this product is to be used once a day (every 24 hours), every day for 14 days</li> <li>it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours</li> <li>14-Day Course of Treatment</li> <li>swallow 1 tablet with a glass of water before eating in the morning</li> <li>take every day for 14 days</li> <li>do not take more than 1 tablet a day</li> <li>do not crush tablets in food</li> <li>do not crush tablets in food</li> <li>do not use for more than 14 days unless directed by your doctor</li> <li>Repeated 14-Day Courses (if needed)</li> <li>you may repeat a 14-day course every 4 months</li> <li>do not take for more than 14 days or more often than every 4 months unless directed by a doctor</li> <li>children under 18 years of age: ask a doctor</li> </ul>
<ul> <li>wartarin (blood-tillinning medicine)</li> <li>prescription antifungal or anti-yeast medicines</li> <li>diazepam (anxiety medicine)</li> <li>digoxin (heart medicine)</li> </ul>	<b>Other information</b> • read the directions, warnings and package insert before use





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