

**Attachment 2**

# Prilosec

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

## OTC™

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

### How Prilosec OTC Works For Your Frequent Heartburn

Prilosec OTC works differently from other OTC heartburn products, such as antacids and other acid reducers. Prilosec OTC stops acid production at the source – the **acid pump** that produces stomach acid. Prilosec OTC is to be used once a day (every 24 hours), every day for 14 days.

### What to Expect When Using Prilosec OTC

Prilosec OTC is a different type of medicine from antacids and other acid reducers. Prilosec OTC may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours. Make sure you take the entire 14 days of dosing to treat your frequent heartburn.

### Safety Record

For years, doctors have prescribed Prilosec to treat acid-related conditions in millions of people safely.

### Who Should Take Prilosec OTC

This product is for adults (18 years and older) with **frequent heartburn**—

when you have heartburn 2 or more days a week.

- Prilosec OTC is **not** intended for those who have heartburn infrequently, one episode of heartburn a week or less, or for those who want immediate relief of heartburn.

### How to Take Prilosec OTC

#### 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.

It is important not to chew or crush these tablets, or crush the tablets in food. This decreases how well Prilosec OTC works.

#### When to Take Prilosec OTC Again

**You may repeat a 14-day course of therapy every 4 months.**

#### When to Talk to Your Doctor

Do not take for more than 14 days or more often than every 4 months unless directed by a doctor.

### Warnings and When to Ask Your Doctor

**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

**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.

### 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.

### How is Prilosec OTC Sold

Prilosec OTC is available in 14 tablet, 28 tablet and 42 tablet sizes. These sizes contain one, two, and three 14-day courses of treatment, respectively. Do not use for more than 14 days in a row unless directed by your doctor. For the 28 count (two 14-day courses) and the 42 count (three 14-day courses), you may repeat a 14-day course every 4 months.

### For Questions or Comments About Prilosec OTC

Call 1-800-289-9181