

# Chain Pharmacist Practice Memo

Volume 7, Number 14

**Special Issue: Omeprazole 20 mg**

SEPTEMBER 2003

Prescription and over-the-counter treatments

*An important counseling opportunity for pharmacists*

The approval of Prilosec OTC (omeprazole magnesium) 20 mg over-the-counter (OTC) is a first: The first OTC proton pump inhibitor approved in the same strength as the prescription formulation. OTC omeprazole will be available in September 2003. Many patients seeking relief from heartburn may decide to purchase this product or ask their pharmacist for advice. This unique situation will prompt questions from patients and allow pharmacists to offer valuable guidance.

## Inside this issue...

- ❖ Major differences between prescription omeprazole 20 mg and the new over-the-counter formulation.
- ❖ Differences between OTC omeprazole, H<sub>2</sub> antagonists, and antacids in treating heartburn symptoms.
- ❖ The warning signs of gastroesophageal reflux disease (GERD): How they differ from heartburn... and when to refer patients to a physician.
- ❖ The complications associated with untreated GERD.

## Three major differences: chemical and indications and dosing

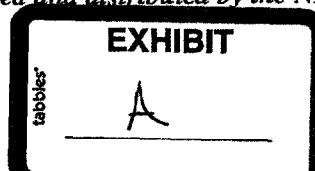
- ❖ **Chemical:** the OTC and prescription versions are not the same. While both contain 20 mg of omeprazole, the OTC tablet is omeprazole **magnesium** and the prescription formulation is a capsule containing omeprazole **sodium**. OTC omeprazole is not AB-rated to prescription omeprazole.
- ❖ **Indications:** OTC omeprazole has a limited indication: frequent heartburn, occurring two or more days per week. Prescription omeprazole is approved to treat frequent heartburn associated with gastroesophageal reflux disease (GERD), but is also indicated for more serious conditions including duodenal or gastric ulcers, treatment and maintenance healing of erosive esophagitis, and pathological hypersecretory conditions all of which require diagnosis and management by a physician.

*Patients who have one or fewer heartburn episodes per week or who seek immediate relief from heartburn symptoms should not use OTC omeprazole.*

- ❖ **Dosing:** OTC omeprazole is FDA-approved to be dosed for 14 consecutive days, once every 4 months unless directed otherwise by a physician. Prescription omeprazole can be dosed chronically, and many patients take it every day.

Pharmacists will play a vital role in helping patients understand the important distinctions between OTC omeprazole and other OTC treatments for heartburn.

*Produced and distributed by the NACDS Foundation*



## PPIs are not “rapid relievers” of heartburn

**I**t is important to advise patients that, unlike other OTC products for heartburn, such as antacids and H2 antagonists, proton pump inhibitors do not provide rapid relief of heartburn.

Antacids neutralize stomach acid and H2 antagonists quickly work to shut down acid secretion in the stomach. However, PPIs work by inhibiting the cause of excess stomach acid secretion, the “proton pump,” and their onset of action is generally one to four days.

*The onset of action of OTC omeprazole is generally one to four days... It is not effective for rapid heartburn relief or for preventing heartburn after eating a meal.*

## Unlike H2 antagonists, PPIs do not prevent heartburn when taken prior to a meal

**S**ome OTC H2 antagonist advertisements inform patients that the medication can be used to prevent heartburn if taken prior to a meal, especially if the patient plans to overindulge or eat a meal with foods known to trigger heartburn. OTC omeprazole cannot be taken before a meal to prevent heartburn from occurring after a meal.

During counseling, pharmacists may wish to advise patients that OTC omeprazole is approved to reduce the frequency of heartburn, but not to relieve symptoms rapidly and not to prevent heartburn by taking it prior to eating a meal.

## Antacids, H2 antagonists, and PPIs: What’s the difference?

**Antacids** provide rapid relief within minutes by neutralizing stomach acids, but their effect generally lasts for less than an hour. Antacids should only be used to relieve mild, infrequent heartburn or indigestion, and are usually taken after meals.

**H2 antagonists** can be used to prevent or relieve mild heartburn. These agents should be taken 15 minutes to one hour before eating or drinking “trigger” foods. H2 antagonists take 30 to 45 minutes to work, but last up to four to eight hours. Long term use of H2 antagonists usually does not heal esophagitis.

**OTC PPI** can be used to treat frequent heartburn that occurs intermittently. This medication should be taken 15 to 30 minutes prior to eating because it works best when taken before eating. The onset of action is generally one to four days.

**Prescription PPIs** provide the best long-term management in relieving moderate to severe heartburn. PPIs are the drug of choice in patients with moderate to severe or frequent symptoms because they accelerate symptom relief and esophageal healing. Long-term PPI therapy to control symptoms of GERD and prevent complications is appropriate.

## **OTC omeprazole use should be limited to 14 consecutive days, once every 4 months**

**O**TC omeprazole should be used no longer than 14 consecutive days, once every 4 months unless directed otherwise by a physician. The product will be available in 14-count, 28-count and 42-count package sizes. so pharmacists may wish to make sure patients are aware of the 14-day limit. If symptoms persist or return after 14 days, patients should consult their physician.

## **Prescription omeprazole can be used for extended periods of time**

**P**rescription omeprazole can be used for an extended period of time. Depending on the condition being treated, the duration of therapy for prescription omeprazole is usually four to eight weeks. Patients who are using the prescription formulation of omeprazole to maintain healing of ulcers may remain on the therapy indefinitely.

## **Prescription omeprazole allows flexible dosing options**

**O**TC omeprazole is available only as a 20 mg tablet which cannot be crushed or chewed. Prescription omeprazole is available in capsule form of 10 mg, 20 mg, and 40 mg. For patients with difficulty swallowing capsules, the capsules may be opened and the contents sprinkled on applesauce as an alternate form of dosing.

## **Patients self-medicating with OTC omeprazole may be at risk of complications**

**O**meprazole sodium will remain as a prescription drug because the conditions it is used to treat (see page 1, "Indications") require diagnosis and medical management with careful monitoring by a physician.

OTC omeprazole is not a replacement for prescription omeprazole. Pharmacists should advise patients currently taking prescription omeprazole not to switch to the OTC version without first consulting their physician.

Symptom severity or duration is not always associated with disease severity. Some GERD patients with severe symptoms may mistake their condition for heartburn and not consult their physician. Those who self-medicate with the OTC product may mask an underlying condition if not properly diagnosed. While only a physician can accurately diagnose GERD, here are a few key warning signs that indicate a patient may have more than simple heartburn and need to see a physician:

- ❖ Patients experience heartburn two or more days per week;
- ❖ Patients do not obtain relief or symptoms worsen while taking OTC heartburn relieving agents;
- ❖ Patients experience heartburn for more than 14 consecutive days and/or more than three times per year.

Complications of untreated GERD can be serious. These may include bleeding ulcers in the esophagus and blockage that may cause food to get stuck in the esophagus. Lung and throat problems such as asthma, aspiration pneumonia, or even permanent lung damage may complicate GERD, and Barrett's esophagus, which may lead to cancer of the esophagus, may develop.

## Omeprazole elevates stomach pH: possible drug interactions

Since omeprazole increases stomach pH, patients taking prescription or OTC omeprazole may have decreased absorption of medications that require an acidic pH to be absorbed, ketoconazole for example. Omeprazole also interacts with warfarin and diazepam, because they are metabolized by the same enzyme, increasing the effects of the latter medications. Digoxin bioavailability may also be increased.

### Minor adverse effects

Adverse effects associated with both forms of omeprazole are generally minor and include headache, vomiting, nausea, diarrhea, abdominal pain, and dizziness.

### Warnings

Patients who are allergic to omeprazole should not take either the OTC or prescription version.

In addition to hypersensitivity, patients who have trouble or pain swallowing food, vomiting with blood, or have bloody or black stools should not use OTC omeprazole. Pharmacists should encourage these patients to consult their physician rather than try to treat their condition themselves. Patients should also consult their physician if they have had heartburn for over 3 months; heartburn with lightheadedness, sweating or dizziness; chest pain; frequent wheezing; unexplained weight loss; nausea or vomiting; and, stomach pain.

*For patients using prescription omeprazole, physicians will be monitoring their patients for these and other conditions and prescribing omeprazole appropriately.*

### Prescription omeprazole dosing tips

*Patients should take omeprazole prior to eating. The capsule should be swallowed whole except in patients who may have difficulty swallowing. These patients can open the contents of the capsule into a tablespoon of applesauce and take it without chewing. The patient should follow the dose with a glass of cool water to ensure complete swallowing of the capsule pellets. The pellet/applesauce mixture should not be saved for later administration. The OTC tablet must be swallowed whole and should not be crushed or chewed.*

The pharmacist is ideally suited to help patients understand these important differences between OTC omeprazole and prescription omeprazole and the appropriate use of OTC and prescription omeprazole.

**Prescription omeprazole will still be covered by most insurance plans**

*Because of the major differences in approved indications and dosing between the prescription and OTC formulations of omeprazole, most insurance companies will continue to cover prescription omeprazole.*

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