The prevalence of heartburn in Western adult populations has been reported to be 20%-40%.1 Of those who suffer from heartburn, up to 27% have reported weekly symptoms.2 Among those who have reported having symptoms of heartburn, 63% report difficulty sleeping and 40% indicated heartburn affects their daily functioning.3 Patients having symptoms of heartburn, 63% report difficulty sleeping and 40% indicated heartburn affects their daily functioning.3 Patients are likely to self-diagnose and self-treat heartburn with over-the-counter (OTC) medications and tend not to seek advice from a healthcare professional. Accurately recognizing the signs of heartburn is an important first step for pharmacists in counseling patients on appropriate OTC medications, since immediate referral to a healthcare professional is necessary if cardiac pain or certain gastrointestinal symptoms are present.4

Goals of Heartburn Treatment
The goals of heartburn treatment are to relieve symptoms and to improve patients’ quality of life. Modifications in lifestyle and avoiding certain activities can help prevent episodes of heartburn. For example, losing weight, quitting smoking, avoiding participating in strenuous physical activity after eating, avoiding restrictive clothing, and avoiding eating for a few hours before bedtime should all be recommended to patients.5-11 Interestingly, refraining from the consumption of foods such as alcohol or coffee, and foods like chocolate, and those that are particularly fatty, acidic, or spicy has often been recommended due to their association with heartburn. However, the American College of Gastroenterology only provides a “conditional recommendation” to eliminate these potential food triggers due to a low level of evidence.12 Pharmacists should advise patients to adopt appropriate lifestyle modifications and encourage patients to personally identify and avoid activities and foods that are known triggers. Unfortunately, avoiding triggers will not prevent heartburn in all patients. In these cases, the use of medication is a necessary step.

Recent Concerns About PPI Treatment
Within recent years, several large, retrospective observational studies have been conducted that have associated chronic PPI use with an increased risk of developing serious adverse events (AEs), such as kidney disease,13 dementia,14 myocardial infarction,15 and bone fractures.16 Although these studies demonstrated a slight increase in risk (odds ratios<2) for these AEs, the clinical significance of the results is unknown. It is important to note that these types of database studies are an exploratory tool used to establish drug safety and identify risks that do not occur in well-controlled clinical trials.17 Any associations that are detected, even if strong, do not confer causality. In the absence of controlled clinical trials to test for these associations, risk assessment should be based on the following: 1) strength of the association, 2) its biological plausibility, and 3) consistency of the evidence. Using these criteria to evaluate risk, several medical experts have agreed that the likelihood of a chronic PPI user developing any of the associated AEs is low. Moreover, those who use OTC PPIs according to the label for the treatment of frequent heartburn are at little to no risk of developing these serious AEs.18

The use of PPIs, as with any drug, has the potential for AEs. This is especially true with long term use and these risks should not be dismissed. However, the potential for these AEs should be put into perspective relative to the large numbers of patients who already take PPIs safely and as directed. The clinical/risk benefit of any medical intervention or therapy should always be evaluated by a healthcare professional and patients counselled on the safe and appropriate use of medications they have been instructed to take. The clinical effects of long term use should always be reviewed and any therapy that is not needed should be discontinued.19

Safety and Efficacy of PPIs
PPIs have been given safely to millions of patients to treat acid-related conditions. The most common adverse effects associated with PPI use are nausea, diarrhea, headache, and rash which occur in 1-3% of patients.20 The frequency of these side effects is comparable to that reported for placebo or for the H2-receptor antagonists. When dosed before meal times, PPIs are the most effective acid inhibitors currently available, and the most widely prescribed class of gastrointestinal medications.21 Four well-controlled, double-blind, randomized clinical studies have been conducted in patients to assess the effects of treating heartburn with two PPIs at daily doses and durations currently approved for OTC use. Two of the studies compared omeprazole 20 mg versus placebo for 14 consecutive days; and two different studies compared esomeprazole 20 mg versus placebo administered for 14 consecutive days.22-23 In all four of these studies, both omeprazole and esomeprazole were superior to placebo in preventing heartburn.

How Should OTC PPIs be Used by Patients?
When OTC PPIs are recommended, pharmacists should review instructions with the patient to ensure their proper use; patients should be advised to follow the label instructions accurately and take one pill per day in the morning as part of a 14-day course of therapy. When taken as directed, OTC PPIs treat frequent heartburn for 24 hours. OTC PPIs are meant for short-term use only; the 14-day regimen can be repeated once every 4 months. Patients must be instructed that any longer-term plan for OTC PPI use should be discussed with their healthcare professional, as heartburn that continues or recurs could be a sign of a more serious issue.

Pharmacists are ideally positioned to help guide patients to appropriate treatment for their heartburn by confirming the diagnosis, referring patients with alarming symptoms to healthcare professionals, and educating patients on the appropriate use of OTC PPIs. This also includes initiating conversations with patients about PPI use and addressing any questions patients may have about their safe and appropriate use. Encouraging open and honest communication with patients is essential to ensure their heartburn is treated properly and safely.

The Pharmacists Guide to Heartburn and Proton Pump Inhibitors

<table>
<thead>
<tr>
<th>Pharmacological Options</th>
<th>MOA</th>
<th>Pros &amp; Cons</th>
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<tbody>
<tr>
<td>Antacids</td>
<td>Act locally by buffering gastric and esophageal contents</td>
<td>Pro: Rapid onset of action; good for treating mild and infrequent heartburn Con: Short duration of action; potential for overdose and hypercalcemia</td>
</tr>
<tr>
<td>Histamine2 receptor antagonists (H2RAs)</td>
<td>Inhibit acid secretion by competitively and reversibly blocking parietal cell histamine, receptors</td>
<td>Pro: Acid suppression for 4-8 hours; well-tolerated Con: Tolerance to the acid-suppressant effects of H2RAs can develop within 2 weeks</td>
</tr>
<tr>
<td>Proton Pump Inhibitors (PPIs)</td>
<td>Inhibits gastric acid secretion by blocking the H+K+ATPase pump</td>
<td>Pro: Highly effective in treating conditions related to excess gastric acid secretion (incl. heartburn) Con: Slow onset of action</td>
</tr>
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Heartburn is a painful, burning sensation in the lower chest that occurs when stomach acid refluxes, or flows up, into the esophagus. Heartburn is very common and occurs in over 40% of the adult population with almost 30% experiencing heartburn weekly. Women are more likely than men to suffer from heartburn and the mean age for a patient with frequent heartburn is 31 to 50 years.

Heartburn can interrupt your sleep and affect your quality of life. Heartburn can be caused by eating large meals, stress, lying down or exercising too soon after eating, or by ingesting caffeine, alcohol, mint, chocolate, or acidic foods or juices. Smoking, wearing tight clothing, and being overweight may also trigger heartburn. Making certain changes in your lifestyle, such as avoiding foods that trigger your heartburn or quitting smoking, may provide relief. However, sometimes lifestyle changes are not enough and you will need medication to treat your heartburn.

You can speak with your pharmacist about appropriate OTC treatment options. Be sure to describe your symptoms, including the frequency, nature, and severity of episodes, so they can help guide you to the best course of treatment and/or refer you to a healthcare professional if necessary. This is because frequent heartburn could be a sign of something more serious, such as gastroesophageal reflux disease, or GERD. Heartburn can be treated with three different types of medications: antacids, H2RA blockers, and proton pump inhibitors, or PPIs. Although these medications all relieve heartburn, when dosed before meal times, PPIs are the most effective acid inhibitors currently available. PPIs block the production of stomach acids that cause heartburn. Many PPIs are now available over the counter (OTC) without a prescription. Although the OTC versions contain the same active ingredient as the prescription forms, the approved dosing for OTC use is typically different. OTC versions of PPIs are indicated for the treatment of frequent heartburn (occurring 2 or more times a week) and are not intended for immediate relief of heartburn, as the drug may take 1 to 4 days for full effect. Prescription PPIs are indicated for the treatment of many other serious acid-related conditions, such as GERD and duodenal and gastric ulcers.

Safety and Efficacy of Heartburn Treatments

PPIs have been given safely to millions of patients to treat acid-related conditions including heartburn. The most common side effects associated with them are headache and diarrhea. You may have also heard recent reports of PPIs being linked to an increased risk of developing other, serious conditions, such as kidney disease, dementia, heart attacks, and bone fractures. However, none of these studies showed that PPIs caused any of these conditions because the data were collected from large databases with a diverse group of patients with many variables (e.g., lifestyle, environment, etc.) that could not be accounted for in the analysis. The conclusions that were drawn were not based on data collected from patients in clinical trials taking PPIs.

How to Use OTC PPIs

If your pharmacist has advised you to take an OTC PPI for frequent heartburn, it is important to follow the label instructions exactly. You should take one pill each day in the morning with a glass of water for 14 days. When taken as directed, OTC PPIs will relieve heartburn for 24 hours. OTC PPIs can only be taken for 14 days and the regimen should not be repeated more often than every 4 months. If your heartburn continues or comes back after 14 days and you feel the need to take OTC PPIs for a longer period of time, consult your pharmacist for advice.

It is important to communicate honestly with your pharmacist and ask them questions about any concerns you may have about the safe and correct use of OTC PPIs. Some suggestions are:

- Can OTC PPIs interact with other drugs I’m taking?
- Can I take OTC PPIs if I’m pregnant?
- What if I miss a day of treatment?
- What do I do if I’m still experiencing heartburn symptoms after 14 days of OTC PPI treatment?

Maintaining open communication with your pharmacist is essential to ensure your heartburn is treated properly so you can live a symptom-free life.

References