

# An Australian pharmacy audit of the management of heartburn and the role of over-the-counter proton pump inhibitors

By John Bell, Associate Professor Peter H Katelaris, George Krassas

## Introduction

Heartburn affects one in five adults regularly<sup>1</sup> and is predominantly self-managed.<sup>2</sup> It is typically described as a feeling of discomfort, burning or pain rising upward from the epigastrium or lower chest,<sup>3</sup> and varies in intensity from occasional mild symptoms to frequent heartburn that adversely impacts the sufferer's quality of life.<sup>4</sup> Proton pump inhibitors (PPIs) are the most effective therapy for the relief of heartburn irrespective of severity<sup>5</sup> and are the most effective treatment for patients with frequent heartburn.<sup>6</sup>

The first over-the-counter (OTC) PPI, *Somac Heartburn Relief* (pantoprazole 20 mg), was introduced in Australia as a *Pharmacist Only Medicine* in 2008. After taking this formulation, 20% of patients are free of heartburn symptoms on day 1; this increases to 74% on day 7 and 84% on day 14.<sup>7</sup> Twelve months after its introduction we conducted a pharmacy audit to assess pharmacy management of this new category of heartburn therapy, to better understand the needs of heartburn patients presenting to pharmacy and to assess the role of OTC PPI treatment.

## Method

A prospective, fixed-time audit was conducted to evaluate the OTC management of heartburn within Australian community pharmacy. A wide geographic spread of pharmacies was recruited into the audit. Participating

pharmacists were given brief instructions relating to the audit process and were asked to audit up to 10 adult people who entered the pharmacy seeking relief of their heartburn or acid-related symptoms. Recruitment of people into the audit was to be capped at 150 respondents.

All people aged 18 years or older presenting to the pharmacist seeking to treat heartburn with an OTC heartburn therapy were eligible for inclusion in the audit. People who were currently using or had previously used prescription therapies for their heartburn or reflux were not automatically excluded from the audit. However, they were only eligible to participate if they were currently seeking advice about the OTC management of their condition.

Consenting people completed a questionnaire about their heartburn. They were then asked to review the information on the back of the *Somac Heartburn Relief* pack to self-assess whether *Somac Heartburn Relief* was suitable for them. In addition, label comprehension as to the correct use of the product was assessed. The pharmacist then conducted their normal consultation and discussed suitable treatment options with the customer. After completing the normal consultation, the pharmacist completed the pharmacist questionnaire before the consumer left the pharmacy. Pharmacists were instructed to fulfill their normal duty of care and that participation in the audit was not to influence therapy recommendation or sale. Participating pharmacies were reimbursed for their time in conducting this audit.

## Results

The audit involved 20 pharmacies located throughout Sydney NSW. They contributed 153 completed surveys. The mean number of surveys completed per

pharmacy was 7.65. The demographics of the audited respondents are summarised in Table 1.

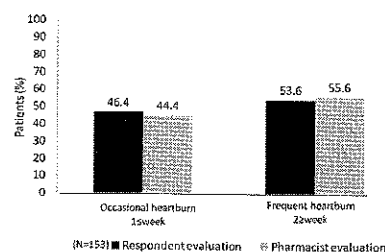
More than half of the respondents presented with frequent heartburn symptoms, occurring two or more times per week (Figure 1).

Half of the respondents rated their heartburn symptoms as moderate or severe (43.8% and 10.5%, respectively) (Figure 2). Despite this profile, the most frequently used previous therapy was antacids

Table 1. Demographic profile of respondents

	N	%
<b>Gender</b>		
Male	66	43.1%
Female	87	56.9%
<b>Age</b>		
<18 years	0	0.0%
18–30 years	48	31.4%
31–54 years	63	41.2%
55 years or older	42	27.4%
<b>Previously seen a doctor for their heartburn</b>		
Yes	83	54.2%
No	70	45.8%

Figure 1. Respondent and pharmacist-assessed frequency of heartburn symptoms

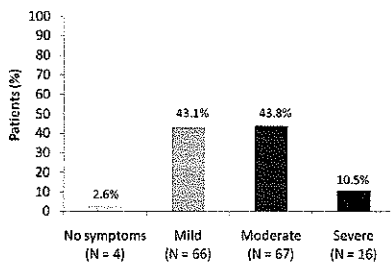


John Bell, Principal Adviser, Pharmacy Self Care, Pharmaceutical Society of Australia. Associate Professor Peter H Katelaris, Gastroenterology Department, Concord Hospital, University of Sydney, NSW. George Krassas, Scius Solutions Pty Ltd, Mosman, Sydney NSW.

Table 2. Previously used heartburn treatments

	N	%
Antacid	81	52.9%
OTC ranitidine	66	43.1%
<i>Somac Heartburn Relief</i>	23	15.0%
Prescription product	41	26.8%
Other	0	0.0%
No product	12	7.8%

Figure 2. Severity of heartburn symptoms



(52.9%), followed by ranitidine (43.1%), with only 15% having previously used *Somac Heartburn Relief* (Table 2).

### Pharmacist evaluation

Results from the pharmacist evaluations indicated that almost all (91.5%; 140/153) respondents seeking OTC heartburn treatment experienced typical heartburn symptoms. Upon completing their assessment, pharmacists determined that *Somac Heartburn Relief* would be suitable therapy for 76.5% (117/153) of the respondents. This was marginally lower than the respondent's self assessment (79.7%; 122/153). Mild symptoms or occasional heartburn were the two most common reasons for the product being considered unsuitable for a particular respondent.

From a safety perspective, pharmacists identified the presence of suspected red flag symptoms in 12.8% (18/153) of respondents. Seven of these were referred to their doctor for further medical assessment. Red flags were specified in eight cases, with the presence of atypical symptoms, the need for continuous therapy for more than four weeks, chest pain, sharp pains, nausea, fatigue, vomiting and symptoms worsening despite

treatment being correctly reported as red flag symptoms. Additional analysis of pharmacist action in these cases saw five of these people being referred to a doctor for further investigation. Of the remaining three cases, one received no product and two were sold ranitidine (one case of worsening symptoms and one case of chest pain). Of the 10 unspecified red flags, only one case of doctor referral was noted. Five respondents were pregnant and none of these was offered *Somac Heartburn Relief* which is consistent with the product information.

Pharmacists identified that concomitant medications may have been contributing to the reflux symptoms in 15.0% (23/153) of respondents. Non-steroidal anti-inflammatory drugs (NSAIDs) were the most common agents (N = 16), of which 57% (9/16) were OTC NSAIDs (ibuprofen or diclofenac). In addition, on three occasions where red flags were identified, NSAIDs were also considered to be contributing to the respondent's reflux symptoms.

Of the 117 (77%) subjects that pharmacists determined were suitable for *Somac Heartburn Relief*, they recommended the product to 105 (69%) and 88 (58%) purchased the product (Figure 3).

### Label comprehension

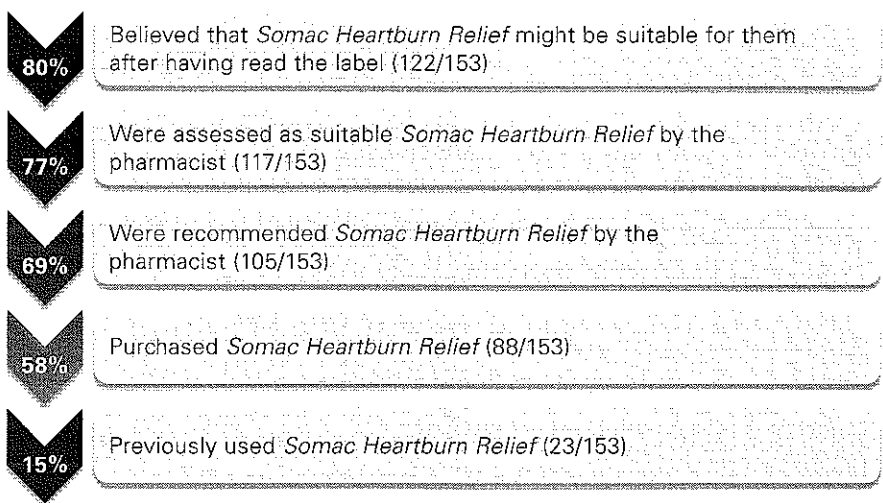
After reading the information on the back of the *Somac Heartburn Relief* packaging, the vast majority of respondents (92.2%, 141/153) were able to correctly identify that the dosing regimen was one tablet per day.

When asked about duration of *Somac Heartburn Relief* therapy before seeking medical advice, 86.3% (132/153) of respondents were able to provide the correct answer. Nine respondents indicated that duration of therapy was one month and 12 answered indefinitely.

### Discussion

In this audit, over half (55.6%, 85/153) of the people coming into the pharmacy seeking treatment for heartburn experienced frequent heartburn (occurring on two or more days per week). The prevalence of frequent heartburn is likely to be an underestimate as 11% (17/153) of subjects reporting only occasional heartburn were either taking or had taken prescription PPIs for their condition. To our knowledge this is the first research to determine the profile of people with heartburn seeking treatment within pharmacy in Australia. As PPIs are recognised as the most effective therapy for frequent heartburn, 1,4-6 there is potential to improve the management of heartburn by pharmacist intervention and recommendation of non-prescription PPIs. The prior use of OTC PPIs in our audit was modest, at only 15% (23/153). This result is not entirely unexpected given that at the time of the audit only one PPI was available OTC and its scheduling had not permitted direct-to-consumer advertising. However, the identified disparity between the number of consumers with frequent heartburn and the number being treated with an OTC PPI indicates that there is a significant opportunity to improve the

Figure 3. The relationship between product suitability and purchasing

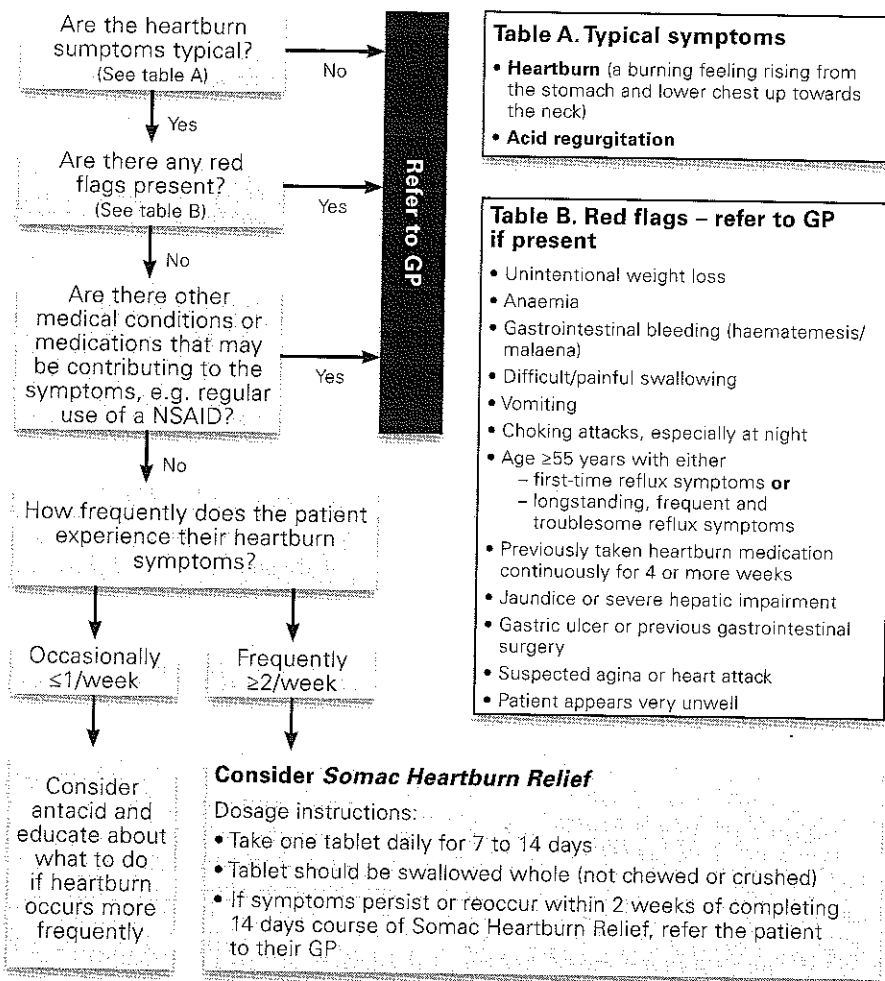


pharmacy management of heartburn. This observation is further supported by the fact that when the respondents in our audit discussed their heartburn with the pharmacist, the purchase of *Somac Heartburn Relief* increased to 58% (88/153).

The audit results have demonstrated that pharmacists can appropriately assess and manage people presenting with frequent heartburn. Pharmacists' recommendations were consistent with the product information and a treatment algorithm specifically developed to facilitate the appropriate supply of *Somac Heartburn Relief* (Figure 4). The majority (91.5%, 140/153) of people presented with typical heartburn symptoms and were free of signs or symptoms (red flags) that would necessitate further medical review before commencing short-term symptomatic treatment. When red flags were identified and specified, most people were referred to their doctor for further investigation. A limitation of this audit was that when red flags were identified, information on pharmacist referral to a doctor was collected via voluntary comment rather than in direct response to a specific question. This was done to avoid biasing the findings of the audit, however it may have resulted in the under-reporting of doctor referral rates, especially amongst those cases where the nature of the red flag was not specified. In all cases where red flags are suspected it is essential that the pharmacist refers the person on for medical review.<sup>9</sup> Pregnant women were managed appropriately and none was offered PPI therapy.

Although this audit did not assess the use of *Somac Heartburn Relief* by customers who purchased the product, we investigated label comprehension as a surrogate marker as to whether usage would be as instructed. Comprehension of the label was excellent, with 92% (141/153) of respondents correctly determining the daily dosage and 86% (132/153) correctly determining that the maximum duration of use was 14 days. For those consumers who deviated from the labelled instructions, the majority had previously used prescription PPIs and hence their previous experience (which allows longer duration of therapy and at higher doses) may have influenced their responses. Even though *Somac Heartburn Relief* is a *Pharmacist Only* medicine and consumers cannot self select the product, it was reassuring that the customer's assessment of

Figure 4. *Somac Heartburn Relief* treatment algorithm



product suitability was in agreement with the pharmacist's assessment in 86% (132/153) of cases.

### Conclusion

Heartburn is a common, predominantly self-managed, condition with many consumers self-selecting products that are available outside the pharmacy. In our audit more than half of the subjects suffered frequent heartburn, for which PPIs are an effective first-line therapy, but only 15% had previously used *Somac Heartburn Relief*. In addition, approximately one in 20 consultations with the pharmacist resulted in a doctor referral. This opportunity for medical intervention is missed amongst those consumers who currently do not seek pharmacist advice for their heartburn. The results of this audit demonstrate that pharmacists seem able to manage the use of *Somac Heartburn Relief* appropriately, in a manner consistent with the product labelling. From a wider

public health perspective, the results also suggest that benefit may be gained from increased consumer awareness of the availability of OTC PPIs and of the pharmacist as a source of advice.

### References

1. Shenfield G, et al. Therapeutic Guidelines Gastrointestinal (4th ed). Therapeutic Guidelines, 2006.
2. Sayer GP, Britt H, Horn F, et al. Measures of health and healthcare delivery in general practice in Australia SAND supplementary analysis of nominated data 1998-99. Australian Institute of Health and Welfare, 2000. Report No.: General Practice Series 3.
3. Digestive Health Foundation. Facts about ... Heartburn oesophageal reflux (3rd ed). 2007.
4. Gastroenterological Society of Australia. Gastro-oesophageal reflux disease in adults Guidelines for clinicians (3rd ed). 2001. At: [www.gesa.org.au/pdf/RefluxDisease1Ed07.pdf](http://www.gesa.org.au/pdf/RefluxDisease1Ed07.pdf) [accessed Mar 5, 2008].
5. Australian Medicines Handbook. Adelaide: AMH, 2008.
6. Inadomi JM, Fendrick AM. PPI use in the OTC era: who to treat, with what, and for how long? Clin Gastroenterol Hepatol 2005 Mar;3(3):208-15.
7. Gatz G. Comparison of the efficacy and tolerability of pantoprazole (20mg/day) and lansoprazole (15mg/day) in patients with mild gastroesophageal reflux disease (stages 0 and 1 according to Savary/Miller). Research Report 301/98. 1999.
8. Haag S, Andrews JM, Katelaris PH, et al. Management of reflux symptoms with over-the-counter proton pump inhibitors: issues and proposed guidelines. Digestion 2009;80(4):226-34.