

## **2 Characterization of Heartburn Consumer**

It is widely acknowledged that heartburn is a common condition, and is easily self-recognized and self-treated within the general consumer population. Antacids have been available for decades as an OTC therapy for the relief of heartburn, while H<sub>2</sub> receptor antagonists have been available to the OTC population for at least 5 years for both the relief and prevention of heartburn.

To supplement this understanding, the Sponsor has surveyed nearly 13,000 consumers within the past 3 years to gain a more thorough understanding of the OTC heartburn remedy user and to understand how this condition is experienced. Data on the OTC heartburn consumer profile, the prevalence of heartburn episodes, patterns of OTC medication usage, health care professional consultation, and satisfaction with the currently available OTC medications were analyzed. In addition, data from other public surveys and literature was thoroughly evaluated, bringing the total number of consumers surveyed to over 140,000.

### **2.1 The Heartburn Sufferer**

On average, the incidence of heartburn in the general population is about 44% (110 million Americans), with a reported range of 24%-73%.<sup>1-16</sup> While heartburn can occur at any age, the typical heartburn sufferer has a mean age in the mid-40's. The incidence of heartburn also appears to increase with age. The occurrence appears to be roughly equal between men and women.

### **2.2 The OTC Heartburn Consumer**

Within the heartburn population frequency of heartburn varies widely, from those who experience heartburn as infrequently as once per year to those who experience heartburn almost on a daily basis.<sup>1,2,3,4,6,7,11</sup> Heartburn is reported most frequently in the evening: about 50%-60% of consumers report late afternoon or evening heartburn and about 30% specifically reported nighttime heartburn.<sup>2,3,8</sup>

A representative US adult OTC heartburn population (n=1,000) was asked to recall their heartburn occurrence over the past 12 months.<sup>7</sup> These are consumers who report taking OTC remedies to treat their heartburn symptoms. About 30% of consumers reported heartburn less than six times per year. More than 40% of consumers reported experiencing heartburn at least once per week, with many reporting heartburn on consecutive days. In this survey, the mean number of reported heartburn episodes was 1.6 times per week. When only consumers who used H<sub>2</sub> receptor antagonists are considered, the curve is shifted to the right: average reported occurrence of heartburn among this population was 2.5 times per week. Nearly 86% of heartburn sufferers report using OTC heartburn medication.<sup>3</sup>

Although OTC heartburn remedies are widely available, many consumers continue to consult a physician. In consumers who suffered heartburn within the past 3 months, 42% saw a physician for the condition and, of these, 56% received a recommendation for an OTC product.<sup>3</sup> An

additional 20% consulted with a pharmacist. In the survey only 9% of the consumers said it was “OK to use an OTC remedy every day without checking with a doctor.”<sup>3</sup> Oliveria *et al.* also reported on health care professional consultation, indicating that in their survey population 55% of male respondents and 66% of female respondents had seen a physician for their heartburn.<sup>2</sup> The authors further noted that those with more severe symptoms were more likely to see a physician.

### **2.3 Self-Diagnosis of Heartburn**

Heartburn is readily self-diagnosed. Ninety-three percent of consumers surveyed stated they could readily identify the symptoms of heartburn and could associate the symptoms with heartburn.<sup>1</sup> Over half of the consumers characterized heartburn as a burning or pain in the esophagus/chest behind the breastbone. Others characterized heartburn as the need to belch, acid back up, a sour taste in the throat, sour stomach, or nervous stomach. Consumers also report that a variety of factors cause their heartburn, most notably food and beverage.

In addition to being a self-recognizable condition, 42% of OTC heartburn sufferers stated they can accurately predict heartburn one hour in advance — 55% among consecutive day sufferers.<sup>3</sup> Among those who predict, 52% took OTC heartburn products preventatively. Clinical data (Appendix 1 of this document) confirms that consumers who predict occurrence of heartburn on any given day can do so with great accuracy. The accuracy was high regardless of whether heartburn was predicted 10–14 times or 1–3 times over the 14-day period. The consumer’s accuracy on days they predict they will have heartburn not only supports that consumers understand their heartburn experience very well but supports that consumers do not take heartburn medicines on a preventative basis needlessly.

### **2.4 Effects on Normal Activities**

While not a life threatening condition, consumers who suffer from heartburn report disturbance of normal activities that inhibits their food choices, increases their irritability, increases sleep disruption, and curtails many normal activities. In consumer research studies, 70% of consumers reported that “heartburn makes it difficult to enjoy life,” 60% reported “disrupted sleep at night so they had less energy the next day,” and 53% reported heartburn “made it harder to do what you were doing.”<sup>15,16</sup> To compensate, consumers have developed a variety of non-pharmacologic “coping” mechanisms to reduce their heartburn. These include propping up the bed or sleeping in a chair, eating only before 6:00 PM, avoiding stressful situations, and avoiding exercise. Even with these measures, many consumers still get heartburn.

### **2.5 Consumer Needs**

Despite the widespread use of these OTC heartburn remedies, consumers report they are still seeking heartburn therapies that provide improved duration of relief, complete prevention of symptoms, and dosing convenience. In fact, 55% of OTC consumers specifically state they need “a medicine they could take once a day to prevent heartburn for 24 hours.”<sup>3</sup> Thus, there is a continuing need for an OTC heartburn medicine that can provide complete 24-hour relief/prevention with the convenience of a single tablet.

## **2.6 Summary**

OTC heartburn consumers are well aware of the condition and factors they believe are associated with their symptoms. They are willing to seek medical advice and are sophisticated in their ability to treat and prevent their own heartburn. These consumers are also generally dissatisfied with the current level of heartburn control available to them and are seeking products that provide a longer duration of relief and more complete prevention of symptoms.