

New Advances with Simethicone

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INTRODUCTION

Over-the-counter simethicone has an established safety history. However, clinical investigations into recent advances, such as combining simethicone (for abdominal gas) with antacids (for indigestion and heartburn), and for postoperative gas pain or during endoscopic examination are lacking. Two studies were initiated in 2015.

Study #1

The first study is investigating the presence of bubbles in the stomach and duodenum during an esophagogastroduodenoscopy examination and whether 250 mg simethicone will reduce the prevalence of those bubbles.

Forty subjects were randomized to receive either no treatment or a 250-mg softgel 15 to 30 minutes prior to examination. Two gastroenterologists, blinded to the group assignment, graded the presence of bubbles and segment visualization during the EGD examination based on the following scale:

The study has concluded and final results are pending comprehensive analysis.

Protocol FP215.05 and CLIN-RPT-197

Study #2 – Investigation of a New Combination Simethicone-Calcium Carbonate Coated Chew for Gas and Heartburn

The second study was an open-label, non-randomized, single-site study that evaluated subjects' acceptability and tolerability of a new OTC 250-mg simethicone plus 750-mg calcium carbonate coated chew for gas/HB symptoms.

Adults with self-described gas/HB occurring at least 2x/week were included if they took one or more OTC product(s) within the past 30 days. Exclusion criteria included patients under a physician's care for gas/HB, use of proton-pump inhibitors (Rx), or use of other Rx products for gas/HB. Baseline assessments included subject's self-reported number of gas/HB events per week and OTC product(s) typically used for their gas/HB symptoms.

Forty-nine subjects (15 males, 34 females; mean age 49 ± 16.3 years, range 18-78 years) were allowed up to 2 coated chews per day during the 7-day study period. Subjects were required to consume at least 1 chew per day, either in response to a gas/HB event or by the end of the day if no symptoms occurred.

After seven days, subjects completed a questionnaire grading organoleptic attributes of the coated chews and self-rated gas/HB relief on a 5-point Likert scale.

BASELINE

Subjects reported using 14 different OTC products or remedies for symptomatic relief of gas/HB.

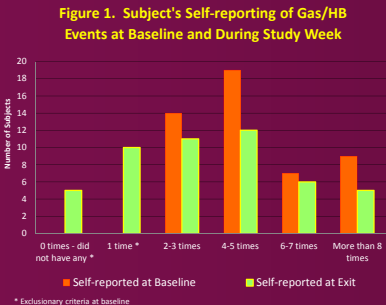
The most frequent, inappropriately used product was single active calcium carbonate (TUMS) that

was reported by 39 subjects as used for the relief of both gas and heartburn.

Self-reported gas/HB events at baseline were: 2-3/week (29%); 4-5/week (39%); and ≥6/week (33%).

SELF-REPORTED SYMPTOMATIC RELIEF

Figure 1 illustrates baseline and post-study self-reported gas/HB events. During the 7-day study, self-reported gas/HB events were: ≤1/week (31%); 2-3/week (22%); 4-5/week (24%); and ≥6/week (22%).



Forty-four subjects experienced gas/HB during the study, and self-reported heartburn relief (77%), and gas relief (70%) after using the coated chews.

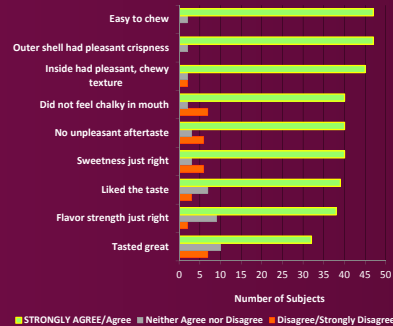
Self-reported time to relief of symptoms was <5 minutes (20%), 5-14 minutes (32%), 15-30 minutes (32%), >30 minutes (5%), and no relief (11%).

Among the 46 subjects who used OTC products for BOTH gas/HB, 63%, including 24 TUMS users, reported greater satisfaction with the new coated chews than their typically used product(s) or remedies.

ORGANOLEPTIC ASSESSMENT

All forty-nine subjects completed the organoleptic assessment (Figure 2).

Figure 2. Subject's Assessment of Individual Organoleptic Attributes (n=49)



Texture attributes (easy to chew – 96% and pleasantly chewy – 92%) were generally rated higher than taste attributes (sweetness just right – 82% and flavor strength just right – 78%). Subjects generally 'liked the taste' (80%) and reported no unpleasant aftertaste (82%) or chalky taste (82%).

CONCLUSIONS

This open-label investigation confirmed the acceptability of a new 250-mg simethicone plus 750-mg calcium carbonate coated chew as an OTC treatment for gas and heartburn.

A majority of subjects reported the inappropriate use of OTC antacid products for relief of gas. Availability of a combination anti-gas, antacid product might offer targeted relief for patients with both symptoms.

Specific findings included:

- A combination simethicone *plus* calcium carbonate coated chew successfully relieved gas (70%) and heartburn (77%)
- Time to symptomatic relief was <30 minutes in 84% of subjects
- 80% of subjects liked the taste
- 82% reported no unpleasant aftertaste or chalky taste
- 61% (24/39) of TUMS users were more satisfied with the coated chews

Investigation Limitations

Study #2 limitations included: single site study, subjective assessments by participants, and descriptive statistical assessment only.

CONTACT INFORMATION

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