# New Advances with Simethicone: Investigation of a New Combination Simethicone – Calcium Carbonate Coated Chew for Gas and Heartburn

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## Introduction

Over-the-counter (OTC) 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), are lacking. We investigated a new simethicone plus calcium carbonate combination agent for relief of gas/bloating and heartburn (gas/HB).

## Methods

This was an open-label, non-randomized, single-site study that sought to evaluate 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.

Qualified subjects 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.

## Methods (cont.)

After 7 days, subjects completed a questionnaire grading organoleptic attributes of the coated chews and self-rated gas/HB relief on a 5-point Likert scale.

Results were assessed using qualitative and descriptive analyses.

## Results

Forty-nine subjects completed the study: 15 males, 34 females; mean age 49 ± 16.3 yrs, range 18-78 yrs.

Subjects reported using fourteen different OTC products or remedies for symptomatic relief of gas/HB. The most frequent, inappropriately used product was single active calcium carbonate (TUMS) for the relief of both gas and heartburn.

In one instance, a product (Prilosec) was dosed per labeled instructions, in all other instances subjects self-prescribed the OTC products PRN.

**Table 1. OTC Products/Remedies Self-prescribed by Subjects for Symptomatic Relief of Gas/HB**

(n = number of subjects; some subjects used more than one product)

| Product/Remedy | Used as BOTH Anti-gas & Antacid (n=46) | Used as Anti-gas (n=8) | Used as Antacid (n=7) |
|---|---|---|---|
| Tums | 39 | - | - |
| Rolaids | 5 | 1 | - |
| Gas-X | 1 | 4 | - |
| Alka Seltzer | 5 | - | - |
| Beano | - | 4 | - |
| Alka Seltzer Chews | 3 | - | - |
| Zantac (ranitidine) | - | - | 3 |
| Pepcid (famotidine) | 1 | - | 1 |
| Pepto Bismol | 3 | - | - |
| Prilosec (omeprazole) | - | - | 2 |
| Other | 2* | - | 1† |
| TOTAL | 59 | 9 | 7 |

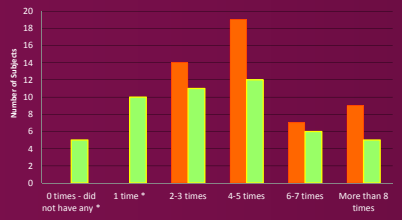
*Equate Antacid, Papaya Enzyme; †milk

## Results (cont.)

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

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

**Subject's Self-reporting of Gas/HB Events at Baseline and During Study Week**




* Exclusionary criteria at baseline

Among the 44 subjects who had gas/HB events during the study period, self-reported relief of symptoms were as follows: relieved heartburn (77%), relieved gas (70%), relieved heartburn quickly (70%), and relieved gas quickly (50%).

Subjects' self-reported time to relief of symptoms after taking a coated chew 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 or remedies for BOTH gas/HB, 63% reported greater satisfaction with the new coated chews than their typically used product(s) or remedies.

## Results (cont.)

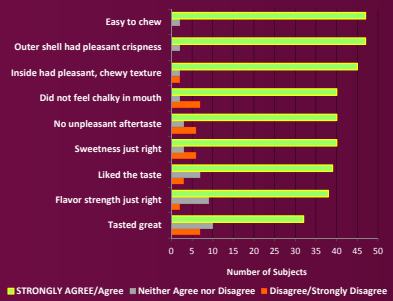
**Table 2. "I am more satisfied with the coated chews than my current product(s)"**

(59 reported uses of products for BOTH gas/HB by 46 subjects [Table 1, Column 1,])

| Product | Strongly Agree | Agree | Neither Agree nor Disagree | Disagree | Strongly Disagree |
|---|---|---|---|---|---|
| Tums | 12 | 12 | 6 | 5 | 4 |
| Rolaids | 3 | - | 1 | - | 1 |
| Gas-X | - | - | 1 | - | - |
| Alka Seltzer | 2 | - | 2 | 1 | - |
| Alka Seltzer Chews | 2 | - | 1 | - | - |
| Pepcid (famotidine) | - | 1 | - | - | - |
| Pepto Bismol | 2 | - | - | 1 | - |
| Other | 1 | - | 1 | - | - |
| TOTAL | 22 (37.3%) | 13 (22.0%) | 12 (20.4%) | 7 (11.9%) | 5 (8.5%) |

Forty-nine subjects completed the organoleptic assessment. 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%).

**Subject's Assessment of Individual Organoleptic Attributes (n=49)**




## Adverse Events

There were 7 non-serious, drug-related adverse events (AEs) occurring in 5 subjects: abdominal cramping (mild, 1); diarrhea (mild, 1; moderate, 2); constipation (mild, 1; moderate, 1); and nausea (mild, 1). One subject discontinued the coated chews due to mild AEs (abdominal cramping and diarrhea).

There were no serious AEs.

## 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

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



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