

# A Pilot Study to Gather Information on the Usage of an Over-the-counter (OTC) Anti-gas Simethicone Softgel

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## INTRODUCTION

**Background:** Abdominal gas and bloating are common conditions often originating from air swallowed from the nose and mouth or developing as by-products of digestion. However, they may also be symptoms of serious gastrointestinal disease, such as irritable bowel syndrome (IBS) or small bowel bacterial overgrowth.

Whatever the cause, abdominal gas symptoms (bloating, pain, eructation and flatus) occur frequently and can have a significant impact on daily living activities. For many people, symptoms can be distressing enough to cause changes in lifestyle, to require over-the-counter (OTC) anti-flatulent medications, and/or to seek medical care.

The anti-foaming agent simethicone is widely used to relieve abdominal gas symptoms, although few data are available about its usage. For the past 15 years the strongest dosage available was 180 mg, but the FDA monograph permits up to 500 mg simethicone per day (for consumer labeling). A new OTC simethicone product is now available as a 250-mg softgel (Phazyme®).

### Aims:

- To gather information on subjects' abdominal gas experience:
  - Impact on daily activities
  - How subjects treat their abdominal gas symptoms
- To investigate how subjects use an OTC simethicone 250-mg anti-gas softgel PRN, both without and with a low-gas diet

## MATERIALS & METHODS

### Study Design

- Open-label, non-randomized, single-site study
  - No age, gender, or health restrictions
- Gas Questionnaire completed by subjects at 1<sup>st</sup> visit
  - 2 multiple choice questions on past gas treatment strategies
  - 22 daily living activities self-rated by impact from abdominal gas as either *All the time*, *Routinely*, *Occasionally*, *Rarely*, or *Never*
- Daily Diary x 3 weeks recording the type & time of daily foods, beverages and abdominal gas symptoms
  - Week 1 – Baseline
  - Week 2 – Simethicone 250 mg PRN
    - 14 softgels dispensed per subject, not to exceed 2 per day
  - Week 3 – Simethicone 250 mg PRN + low-gas diet
    - Low-gas diet/beverage list handout (suggested to follow)
    - 14 softgels dispensed per subject, not to exceed 2 per day
- Data Evaluations
  - Gas Questionnaire – responses tallied and analyzed descriptively to evaluate effect of abdominal gas on daily activity
  - Daily Diaries were reviewed by a gastroenterologist
  - Gas events & simethicone usage data analyzed descriptively
  - Willingness to use simethicone softgels in the future tallied
- IRB approval received before enrollment (04Sep2013)

## RESULTS – Demographics

- Gas Questionnaire
  - 42 subjects completed the questionnaire (32 F: 10 M)
  - 29 Caucasian, 12 African-American, 1 Hispanic
  - Mean age 53 years (range: 25 – 73)
- Daily Diary
  - 38 subjects completed all 3 weeks (30 F: 8 M)
  - 26 Caucasian, 11 African-American, 1 Hispanic
  - Mean age 54 years (range: 28 – 73)

## RESULTS – Gas Questionnaire

Daily living activities were arranged into 5 categories

Incidence	Gas Questionnaire Categories				
	Altered Food/Drink	Avoided Activity	Worry in Public	Emotional Distress	Other
All questions = yes <sup>a</sup>	64.3%	52.4%	40.0%	40.0%	45.0%
Frequency (calculated scale) <sup>b</sup>	(0 – 20)	(0 – 16)	(0 – 20)	(0 – 16)	(0 – 16)
Mean (± SD) <sup>c</sup>	10.2 (± 4.5)	4.8 (± 2.3)	7.6 (± 4.1)	7.0 (± 4.0)	4.6 (± 3.3)
Median (IQR) <sup>c</sup>	10 (7, 13)	5 (3, 6)	7.5 (5, 10)	6 (4, 9.8)	4 (2, 7)
Range	0 – 19	0 – 9	0 – 17	0 – 15	0 – 12

<sup>a</sup>Yes = all questions in category reported as either *All the time*, *Routinely*, *Occasionally*, or *Rarely*  
<sup>b</sup>For all frequency scales, 0 = least frequent (ie, *Never*) to 16 or 20 = most frequent (ie, *All the time*)  
<sup>c</sup>SD = standard deviation; IQR = 25% and 75% interquartile range

- In each category, the specific activity that subjects reported most frequently (reported as *All the time* or *Routinely*) altered because of abdominal gas
- 50% skipped some of their favorite foods
  - 8% avoided sports or physical activity
  - 45% worried about flatulence in public
  - 40% felt frustrated
  - 15% had been sad/mad because they couldn't do something they enjoyed

## RESULTS – Type of Gas Treatments Used

A variety of medicines/remedies were used as treatment for gas

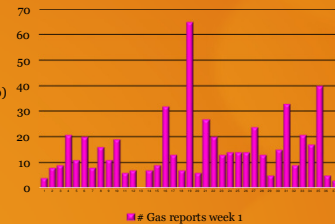
Anti-gas, Anti-flatulent Products (by Active Ingredient)	# Reports
simethicone	22
α-galactosidase (enzyme)	11
antacid (+ anti-gas when combined with simethicone)	2
Other Products (Not Labeled for Abd. Gas Treatment)	# Reports
antacid	9
analgesic, antacid	3
upset stomach, anti-diarrheal	2
infection due to susceptible bacteria	1
prevent / relieve heartburn	1
dietary supplement	3
home remedies	3

- 52% subjects used ≥1 OTC product labeled as anti-gas/anti-flatulent
  - 2% used OTC product that *may* have had anti-gas/anti-flatulent ingredient
- 45% used products **not** labeled for treatment of abdominal gas as treatment for their gas symptoms

## RESULTS – Gas Events & Simethicone 250 mg PRN

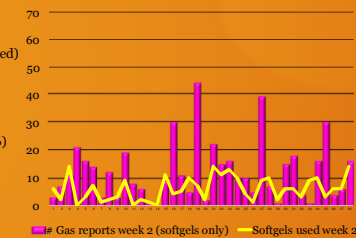
### Week 1 (Baseline)

- Gas event reports
  - 598 total
  - Mean (±SD): 15.7 (±12.4)
  - Median (IQR): 13 (7.3, 20)
  - Range: 0 – 65
- Diet & beverages
  - Fried food: 83 reports



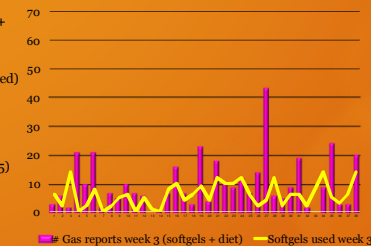
### Week 2 (Simethicone PRN)

- Simethicone softgels used
  - 226 total (42% of dispensed)
- Gas event reports
  - 460 total
  - ↓23% from Week 1
  - Mean (±SD): 12.1 (±10.4)
  - Median (IQR): 10 (4.3, 16)
  - Range: 0 – 44
- Diet & beverages
  - Fried food: 52 reports



### Week 3 (Simethicone PRN + low-gas diet)

- Simethicone softgels used
  - 226 total (42% of dispensed)
- Gas event reports
  - 375 total
  - ↓37% from Week 1
  - Mean (±SD): 9.9 (±8.8)
  - Median (IQR): 7 (3.3, 13.5)
  - Range: 0 – 43
- Diet & beverages
  - Fried food: 45 reports



## RESULTS – Willingness to Use Softgels in Future

- 84% subjects reported they would use simethicone softgels in the future
- 8% would not use simethicone softgels in the future
- 8% did not respond to the question

## ADVERSE EVENTS

- Drug-related – no adverse events (AEs) or serious adverse events (SAEs)
- Self-reported by subjects in daily diaries
  - 3 subjects reported loose stool or diarrhea
  - 1 subject reported mild nausea
  - 1 subject reported 'knot' in upper stomach

## CONCLUSIONS

Abdominal gas has a significant impact on daily activities and may cause unnecessary worry

- Most common self-management is combination of OTC product(s) and dietary changes
  - Simethicone is the most frequently used anti-flatulent active ingredient
  - OTC products **not** labeled for abdominal gas used almost as frequently
  - 64% of subjects reported altering food/drink before study

During 3 weeks of study

- Gas event reports
  - Declined 23% Week 1 to Week 2 (simethicone softgels PRN)
  - Declined 37% Week 1 to Week 3 (simethicone softgels PRN + low-gas diet)
- Diary recording may lead to identification of foods & beverages associated with abdominal gas
- Willingness to use simethicone softgels in the future was high

## RELEVANCE TO GASTROENTEROLOGY NURSING

- Abdominal gas symptoms occur frequently and are typically due to normal conditions
  - Gas symptoms may also be associated with serious gastrointestinal diseases
- Gastroenterology nurses:
  - Need to be alert to self-reporting by patients
  - Should ask patients about abdominal gas as part of a standard diagnostic assessment

## LIMITATIONS

- Gas Questionnaire categories appear suitable for analysis, but need wording clarifications and/or balance by category and recruitment (age, gender) depending on desired outcomes
- Relationship between dietary adjustment and decline in gas requires standardized dietary recording methodology
- Relationship between simethicone softgel usage and decline in abdominal gas needs further investigation