

# Simethicone

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## Continuing Education Activity

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Simethicone is a medication used in the management and treatment of flatulence. This activity describes the indications, mechanism of action, and contraindications for simethicone as a valuable agent in the control of excess gas production. In addition, this activity will highlight the adverse event profile, dosing, and drug interactions pertinent to the interprofessional healthcare team members in the management of patients with flatulence and related conditions.

### Objectives:

- Identify the mechanism of action of simethicone.
- Describe the adverse effects of simethicone.
- Review the appropriate monitoring of simethicone.
- Outline some interprofessional team strategies for improving care coordination and communication. This knowledge will enhance simethicone use and improve outcomes.

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## Indications

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Simethicone is a silicone compound used for the management of flatulence and bloating. It relieves the discomfort produced by the presence of excess gas in the gastrointestinal tract. It was FDA approved in 1952.<sup>[1]</sup> Since then, it has been researched for use as a skin protectant, for treatment of Helicobacter pylori, and most recently in endurance athletes to reduce exercise-related GI symptoms. Researchers also studied simethicone to treat infantile colic, but they did not find it to be effective. Simethicone is not useful for ileus, small bowel obstruction, or constipation. Other causes of such symptoms that could be related to gallstones or heart disease should be kept in mind when utilizing simethicone. Additional signs and symptoms, such as vomiting, hematochezia, and severe abdominal tenderness, require further investigation. Simethicone has also been demonstrated to be safe and well-tolerated as a component of a contrast agent to improve sonographic imaging in the abdomen.

Bernstein and Kasich performed one of the earliest studies of simethicone in 1974. This study was a double-blind, randomized, placebo-controlled trial where they compared simethicone 50 mg to placebo. Placebo was identical in taste and appearance. Inclusion criteria included subjects ranging in age from 21 to 65 years, an outpatient setting, a minimum of two of the symptoms that

were under evaluation. Subjects were enrolled alternately to simethicone or placebo. Forty-one patients were enrolled in the study, with twenty in the simethicone group and twenty-one in the placebo group. The assigned medication was given 10 minutes before each meal and at bedtime for ten days. Changes in symptoms were evaluated around day five and again around day 10. Symptoms evaluated included gas, heartburn, fullness, full feeling, distension, stuffiness, acid indigestion, bloating, pressure, upset stomach, sour stomach, and pain after eating. Symptoms were evaluated by frequency and severity. When comparing the simethicone group to placebo, researchers observed a significant improvement in all symptoms in the simethicone group at visits on day five and day 10.[\[7\]](#)

## Mechanism of Action

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Simethicone is a silicone compound that functions as a non-systemic surfactant, decreasing the surface tension of gas bubbles in the GI tract. This action results in coalescence and dispersion of the gas bubbles allowing their removal from the GI tract as flatulence or belching. Simethicone causes the gas bubbles to accumulate and therefore pass more easily either through the upper GI or lower GI opening. Simethicone does not appear to reduce the actual production of gas in the GI tract.

Simethicone does not inhibit conditions such as lactose intolerance or medication side effects that increase the production of gas bubbles in the gastrointestinal tract. Intestinal gases are composed mostly of nitrogen, oxygen, carbon dioxide, hydrogen, and methane. Simethicone is excreted in the feces.

## Administration

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Simethicone administration is via the oral route. It comes manufactured as tablets, capsules, chewable films, and liquid. Although it is an inert compound, simethicone should not be administered parenterally or through inhalation. It is presumed safe in infants. Initial studies used dosing of 50 mg ten minutes before each meal and at bedtime for ten days. This dosing has now changed to the following recommendations:

Adults: 40 to 125 mg orally four times daily as needed after meals and at bedtime; the maximum daily dose is 500 mg.

Children ages 2 to 12 years: 40 mg orally four times daily as needed after meals and at bedtime; the maximum daily dose is 480 mg.

Children and infants less than two years of age: 20 mg orally four times daily as needed after meals and at bedtime; the maximum daily dose is 240 mg.

Simethicone is available "over the counter" (OTC) medicine. It is manufactured in combination with medications such as aluminum hydroxide, magnesium hydroxide, calcium carbonate, and loperamide.

## **Adverse Effects**

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Simethicone does not have any serious side effects. There have been reports of mild diarrhea and nausea. Since simethicone is not absorbed orally, it is logical that systemic side effects such as kidney injury, hypertension, and hyperglycemia do not occur. Silicosis is a condition of pulmonary fibrosis caused by the inhalation of silica dust (also known as silicon dioxide). Still, there have been no reported cases of silicosis secondary to oral simethicone administration.

## **Contraindications**

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Simethicone is contraindicated in patients with a simethicone allergy.

## **Monitoring**

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Simethicone is not absorbed systemically, so serum simethicone levels would not be feasible. An abdominal x-ray or computed tomography can assist in monitoring outcomes. However, imaging is very rarely needed. Simethicone has no significant drug interactions. There is a case report of changed absorption of levothyroxine in a child when taking simethicone. However, the overall concern is minimal.

Another case report indicated that carbamazepine toxicity could result when administering carbamazepine with simethicone. In that case, a 45-year-old man with epilepsy on carbamazepine underwent evaluation for symptoms of carbamazepine toxicity. He had an elevated serum carbamazepine level of 34.2 micrograms per milliliter (standard 4 to 11) after taking simethicone for two days. The serum carbamazepine level was obtained approximately 8 to 9 hours after his last dose of carbamazepine. His serum carbamazepine level was checked two days earlier and was 10.5 micrograms per milliliter. That was 10 to 11 hours after his previous carbamazepine dose. The patient denied taking any extra dosage, alcohol, herbal products, or any other new medications. In the author's conclusion, they recommended caution when prescribing simethicone in a patient taking carbamazepine.

## **Toxicity**

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Simethicone is not absorbed systemically, so it is safe in pregnancy and breastfeeding. There is no treatment for a simethicone overdose other than stopping the medication.

## **Enhancing Healthcare Team Outcomes**

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Simethicone is a frequently prescribed drug by primary care providers, internists, nurse practitioners, physician assistants, and gastroenterologists to treat flatulence and bloating. A knowledgeable provider can utilize simethicone to improve the patient's symptoms. In the hospital setting, simethicone can be ordered before meals and at bedtime, scheduled four times a day as needed. Hospital workflow and patient cognition is a consideration in inpatient settings. It

can be more beneficial to order simethicone as a scheduled regimen, so the patient receives multiple doses consistently. Simethicone is highly cost-effective in treating bloating and flatulence. It is an OTC product purchased without a prescription. Pharmacists can assist with proper dosing and administration. Nursing can help to improve patient's utilization of simethicone. A dietitian can assist a patient in enhancing their eating habits to avoid carbonated beverages and foods that increase gastrointestinal gas formation. The interprofessional team approach is the best means by which optimal patient outcomes can be achieved when using simethicone therapeutically. Thus, simethicone can help to treat flatulence and bloating safely. [Level 2]

## Review Questions

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