

**Drug Information Provided by Elsevier**

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## Brand Names

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Equalizer Gas Relief, Gas Free , Gas Relief, GasAid, Gas-X, Gas-X Extra Strength, Gas-X Infant, Gas-X Ultra Strength, Genasyme, Gerber Gas Relief, Infantaire, Infants' Gas Relief, Kaopectate, Little Remedies for Tummies, Mylanta Gas, Mylicon, Mytab Gas, PediaCare Infant's Gas Relief, Phazyme, Phazyme ULTIMATE, Reliable-1 Infant's Gas Relief, Teeny Tummy Infant Gas

## Indication Specific Dosing

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**For the symptomatic relief of pressure, bloating, and fullness commonly referred to as gas (flatulence)**

### Oral dosage

#### Adults

40 to 500 mg PO per dose as needed after a meal(s) and/or at bedtime, is the non-prescription dosing. Usual Max: 500 mg/24 hours except under the advice and supervision of a physician.

#### Adolescents

40 mg to 160 mg PO per dose after meals and at bedtime, as needed, is the non-prescription dosing. Usual Max: 480 mg/day PO unless otherwise directed by a physician.

#### Children 2 to 12 years and more than 10.9 kg weight

40 mg PO per dose after meals and at bedtime as needed, or as directed by a physician (non-prescription dosing). Usual Max: 480 mg/day PO unless otherwise directed by a physician.

#### Infants and Children less than 2 years or less than 10.9 kg weight

20 mg PO per dose after meals and at bedtime as needed, or as directed by a

physician (non-prescription dosing). Usual Max: 240 mg/day (12 doses) PO unless otherwise directed by a physician. Efficacy for infant colic is questionable.

## **Oral dosage (Kaopectate oral suspension)**

### **Adults**

125 mg to 250 mg PO per dose as needed after a meal(s) and/or at bedtime, is the non-prescription dosing. Usual Max: 500 mg/24 hours except under the advice and supervision of care team.

## **For the symptomatic relief of functional dyspepsia†**

### **Oral dosage**

#### **Adults**

Doses of 80 to 105 mg PO 3 times per day have been used. Simethicone was more effective than cisapride in the first 2 weeks of dyspepsia treatment for symptomatic relief in one trial. Routine use is not recommended; simethicone has not been included as a standard treatment option in dyspepsia guidelines due to lack of sufficient, high-quality data.

## **For use as an aid in gastrointestinal or bowel preparation† to reduce foaming and enhance visualization during endoscopy†, colonoscopy†, gastrointestinal radiography†, or other GI diagnostic procedures**

### **Oral dosage (simethicone oral suspension)**

#### **Adults**

Simethicone has a long history of use in gastrointestinal (GI) diagnostic procedures. Single doses of 40 mg to 133 mg PO given 20 minutes to 1 hour prior to various endoscopy, colonoscopy, or GI radiographic procedures are most common. Simethicone oral suspension drops are most commonly used. Various protocols are reported, depending on the procedure and institution. Most publications/guidelines agree that the addition of simethicone prior to standard preparation regimens may aid visualization during magnetically controlled capsule endoscopy, upper gastroscopy or endoscopy, colonoscopy, GI radiography, and selected other GI procedures. The effect on diagnostic yield is controversial. Also, simethicone residue despite endoscope reprocessing has been reported.

# Contraindications And Precaution

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## Drug Interactions

The coadministration of certain medications may lead to harm and require avoidance or therapy modification; review all drug interactions prior to concomitant use of other medications.

## Hypersensitivity

This medication is contraindicated in patients with a history of hypersensitivity to it or any of its components.

## phenylketonuria

Some formulations of chewable simethicone tablets contain aspartame, a source of phenylalanine. Check inactive ingredient labels if simethicone is used in individuals with phenylketonuria.

## pregnancy

At normal therapeutic doses for the treatment of occasional gas, simethicone is considered low risk for use during pregnancy. Epidemiologic evidence during human pregnancy shows no difference in outcomes between simethicone exposed and nonexposed pregnancies, and there is a low risk for use during endoscopy or as an antiflatulent because it is not systemically absorbed.

## breast-feeding

Simethicone is compatible with breast-feeding. Although studies have not been conducted to determine if simethicone is excreted in human milk, it is unlikely because it is not absorbed systemically. It is also used safely in breastfed infants.

# Pregnancy And Lactation

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At normal therapeutic doses for the treatment of occasional gas, simethicone is considered low risk for use during pregnancy. Epidemiologic evidence during human pregnancy shows no difference in outcomes between simethicone exposed and nonexposed pregnancies, and there is a low risk for use during endoscopy or as an antiflatulent because it is not systemically absorbed.

# Interactions

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Levothyroxine: (Moderate) Oral thyroid hormones should be administered at least 4 hours before or after a dose of simethicone. Concurrent use may reduce the efficacy of levothyroxine by binding and delaying or preventing oral absorption, potentially resulting in hypothyroidism. Simethicone has been reported to chelate oral levothyroxine within the GI tract when administered simultaneously, leading to decreased thyroid hormone absorption.

Levothyroxine; Liothyronine (Porcine): (Moderate) Oral thyroid hormones should be administered at least 4 hours before or after a dose of simethicone. Concurrent use may reduce the efficacy of levothyroxine by binding and delaying or preventing oral absorption, potentially resulting in hypothyroidism. Simethicone has been reported to chelate oral levothyroxine within the GI tract when administered simultaneously, leading to decreased thyroid hormone absorption.

Liothyronine: (Moderate) Oral thyroid hormones should be administered at least 4 hours before or after a dose of simethicone. Concurrent use may reduce the efficacy of levothyroxine by binding and delaying or preventing oral absorption, potentially resulting in hypothyroidism. Simethicone has been reported to chelate oral levothyroxine within the GI tract when administered simultaneously, leading to decreased thyroid hormone absorption.

Thyroid hormones: (Moderate) Oral thyroid hormones should be administered at least 4 hours before or after a dose of simethicone. Concurrent use may reduce the efficacy of levothyroxine by binding and delaying or preventing oral absorption, potentially resulting in hypothyroidism. Simethicone has been reported to chelate oral levothyroxine within the GI tract when administered simultaneously, leading to decreased thyroid hormone absorption.

# Adverse Reaction

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## eructation, flatulence

Troublesome adverse events reported with simethicone are infrequent; the more common and mild side effects include eructation and flatulence as air bubbles and gas are eliminated from the GI tract. The drug is not absorbed systemically.

# Description

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Simethicone is an oral antiflatulent agent. It is used to relieve the pain and pressure of excess gas in the digestive tract. Although simethicone is widely used and relatively safe,

its efficacy for the treatment of gas is controversial. Simethicone has not been shown beneficial in infant colic vs. placebo. The drug is also used as an antifoaming agent in gastrointestinal (GI) radiographic and other GI procedures to enhance gastrointestinal visibility and reduce gas shadowing. Simethicone-containing nonprescription products have been marketed since the 1950s and the drug is available as a single agent or in combination with products such as antacids or antidiarrheals.

## Mechanism Of Action

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As an antiflatulent, simethicone has been shown in vitro to disperse and prevent the formation of mucus-surrounded gas pockets in the GI tract. Changing the surface tension of the gas bubble prevents these pockets. The gas bubbles coalesce and are more quickly eliminated by flatus, belching, or absorption into the bloodstream. These actions in vivo have not been clearly established. Additionally, simethicone exhibits in vitro activity against *Helicobacter pylori*.

Simethicone also reduces gas bubbles that obstruct visualization in various gastrointestinal procedures such as radiography, gastroscopy, and colonoscopy. For example, simethicone-coated cellulose suspension (e.g., SonoRx) acts to absorb and disperse gas within the bowel lumen resulting in reduced shadowing during ultrasound imaging.

## Pharmacokinetics

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Both simethicone and simethicone-coated cellulose suspension are administered orally. Simethicone is physiologically inert and not systemically absorbed. A study in volunteers measuring silicon in the blood (as the surrogate marker for simethicone) noted that blood and urine levels of silicon were similar at baseline and after receiving SonoRx or vehicle control. This suggests minimal systemic absorption of simethicone. Similarly, the body does not metabolize simethicone and cellulose. Simethicone and cellulose are both excreted unchanged in the feces. Simethicone is not known to interfere with gastric secretion or nutrient absorption; however, this medicine is usually taken after at least 4 hours of fasting. SonoRx may color the stool orange until elimination is complete, typically 24 to 48 hours.

### Route-Specific Pharmacokinetics

- **Oral Route**

Simethicone is physiologically inert and not systemically absorbed.

- **Pediatrics**

Pharmacokinetic studies of simethicone have not been performed in pediatric patients.

- **Elderly**

Pharmacokinetic studies of simethicone have not been performed in geriatric patients.

- **Other**

Patients with impaired bowel motility

In patients with impaired bowel motility, SonoRx (simethicone) ingestion resulted in similar blood and urine silicon levels as normal volunteers. However, the cellulose elimination rate in the feces was decreased compared to normal volunteers. The clinical significance of this finding is not known; however, the manufacturer states that animal studies have noted cellulose accumulation in peritoneal tissues.

## Administration

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For storage information, see the specific product information within the How Supplied section.

### Oral Administration

#### Oral Solid Formulations

Chewable tablets:

Chew tablet well before swallowing.

Softgel or Liquid-filled capsules:

Swallow whole with water; do not chew.

#### Oral Liquid Formulations

Simethicone oral suspension:

Shake well prior to each administration.

Measure each dose with provided calibrated dropper or syringe or other oral calibrated measuring device.

For infants, administer liquid toward the inner cheek of infant.

To ease administration, drops may be mixed with 1 ounce of cool water, infant formula, or other liquids.

## Maximum Dosage Limits

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- **Adults**

500 mg/day PO for nonprescription use.

- **Geriatric**

500 mg/day PO for nonprescription use.

- **Adolescents**  
480 mg/day PO.
- **Children**  
2 to 12 years: 480 mg/day PO.  
1 year: 240 mg/day PO.
- **Infants**  
240 mg/day PO.

## Dosage Forms

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- Advanced Antacid Maximum Strength 800mg-800mg-80mg/10mL Suspension (Cherry)
- Antacid & Anti-Gas Maximum Strength 800mg-800mg-80mg/10mL Suspension (Vanilla Caramel)
- Bicarsim Forte 125mg Chewable Tablet (Mint)
- CVS Antacid Maximum Strength 800mg-800mg-80mg/10mL Liquid (Original)
- CVS Gas Relief 125mg Extra Strength Chewable Tablet (Cherry Creme)
- CVS Gas Relief 125mg Extra Strength Chewable Tablet (Peppermint Creme)
- CVS Gas Relief 125mg Extra Strength Softgel
- CVS Gas Relief 180mg Ultra Strength Softgel
- CVS Gas Relief 80mg Chewable Tablet (Mint)
- CVS Gas Relief 80mg Regular Strength Chewable Tablet (Cherry Creme)
- CVS Infants' Gas Relief 20mg/0.3ml Drops
- CVS Infants' Gas Relief Non-Staining 20mg/0.3mL Drops
- DRx CHOICE Gas Relief 80mg Chewable Tablet (Mint)
- Equaline Gas Relief 125mg Extra Strength Softgel
- Equate Antacid Maximum Strength 800mg-800mg-80mg/10mL Suspension (Cherry)
- Equate Antacid Maximum Strength 800mg-800mg-80mg/10mL Suspension (Original)
- Equate Gas Relief 125mg Extra Strength Softgel
- Equate Gas Relief 125mg Extra Strength Softgel
- Equate Gas Relief 125mg Extra Strength Chewable Tablet (Cherry Creme)
- Equate Gas Relief 125mg Extra Strength Softgel
- Equate Gas Relief 125mg Extra Strength Softgel
- Equate Gas Relief Ultra Strength 180mg Softgel
- Equate Infant's Gas Relief 20mg/0.3ml Drops
- Foster & Thrive Gas Relief 125mg Extra Strength Softgel
- Foster & Thrive Gas Relief 180mg Ultra Strength Softgel
- Foster & Thrive Gas Relief Extra Strength 125mg Chewable Tablet (Cherry)

- Foster & Thrive Gas Relief Regular Strength 80mg Chewable Tablet (Mint)
- Foster & Thrive Infants' Gas Relief 20mg/0.3mL Drops
- Gas Relief 125mg Extra Strength Softgel
- GAS RELIEF 80mg Chewable Tablet (Mint)
- Gas Relief 80mg Chewable Tablet (Peppermint)
- Gas Relief Extra Strength 125mg Chewable Tablet
- GAS RELIEF Extra Strength 125mg Chewable Tablet (Mint)
- Gas-X 62.5mg Thin Strip (Cinnamon)
- Gas-X Extra Strength 125mg Chewable Tablet (Cherry Creme)
- Gas-X Extra Strength 125mg Softgel
- Gas-X Extra Strength Chewable Tablet (Peppermint Creme)
- Gas-X Extra Strength Softgel
- Gas-X Ultimate Strength 500mg Softgel
- Gas-X Ultra Strength Softgel
- GNP Anti-Gas 180mg Ultra Strength Softgel
- GNP Anti-Gas 180mg Ultra Strength Softgel
- GNP Anti-Gas 180mg Ultra Strength Softgel
- GNP Anti-Gas 180mg Ultra Strength Softgel
- GNP Gas Relief 125mg Extra Strength Softgel
- GNP Gas Relief 125mg Extra Strength Softgel
- GNP Gas Relief 80mg Chewable Tablet (Mint)
- GNP Gas Relief Extra Strength 125mg Chewable Tablet (Cherry)
- GNP Gas Relief Extra Strength Chewable Tablet (Cherry Creme)
- GNP Infant Gas Relief 20mg/0.3mL Drops
- GNP Infants' Simethicone 20mg/0.3ml Drops
- GoodSense Antacid & Gas Relief Maximum Strength 800mg-800mg-80mg/10mL Suspension (Original)
- GoodSense Gas Relief 125mg Extra Strength Softgel
- GoodSense Gas Relief 180mg Ultra Strength Softgel
- GoodSense Gas Relief Extra Strength 125mg Chewable Tablet (Cherry Creme)
- GoodSense Infants' Simethicone 20mg/0.3mL Drops
- Health Star Gas Relief 125mg Extra Strength Softgel
- HEALTH STAR Gas Relief Extra Strength 125mg Softgel
- HEALTH STAR INFANTS' GAS RELIEF 20mg/0.3mL Drops
- HEB RX Act Gas Relief Infants' 20mg/0.3mL Drops
- Infants' Gas Relief 40mg/0.6mL Drops
- Infants' Gas Relief Dye Free 20mg/0.3mL Drops
- Kaopectate Gas Relief Extra Strength 125mg/5mL Liquid (Berry)
- Leader Antacid Maximum Strength 800mg-800mg-80mg/10mL Liquid
- Leader Gas Relief 125mg Extra Strength Softgel



- Leader Gas Relief 180mg Ultra Strength Softgel
- Leader Gas Relief 80mg Chewable Tablet (Mint)
- Leader Infants' Gas Relief 20mg/0.3mL Drops
- Little Remedies Infant for Tummies Gas Relief 20mg/0.3mL Drops
- Mylanta Gas Minis Chewable Tablet (Arctic Mint)
- Mylanta Gas Minis Chewable Tablet (Assorted Fruit)
- Mylanta Maximum Strength 800mg-800mg-80mg/10mL Suspension
- Mylanta Maximum Strength 800mg-800mg-80mg/10mL Suspension (Vanilla Caramel)
- MYLICON Infants' Gas Relief 20mg/0.3mL Drops
- MYLICON Infants' Gas Relief 20mg/0.3mL Dye Free Drops
- Phazyme 180mg Ultra Strength Fast Gels Softgel
- Premier Value Gas Relief 125mg Extra Strength Softgel
- Premier Value Gas Relief 180mg Ultra Strength Softgel
- Publix Gas Relief 125mg Extra Strength Softgel
- Publix Gas Relief 180mg Ultra Strength Softgel
- Publix Infants' Gas Relief 20mg/0.3ml Drops
- Quality Choice Gas Relief 125mg Extra Strength Chewable Tablet (Cherry Creme)
- Quality Choice Gas Relief 125mg Extra Strength Softgel
- Quality Choice Infants' Dye-Free Gas Relief 20mg/0.3mL Drops
- Quality Choice Infants' Gas Relief Non-Staining 20mg/0.3mL Drops
- Reliable-1 INFANTS' GAS RELIEF 20mg/0.3mL Drops
- RITE AID Gas Relief 125mg Extra Strength Softgel
- RITE AID Gas Relief 125mg Extra Strength Chewable Tablet (Cherry)
- RITE AID Gas Relief 125mg Extra Strength Chewable Tablet (Mint)
- RITE AID Gas Relief 180mg Ultra Strength Softgel
- RITE AID Gas Relief 80mg Regular Strength Chewable Tablet (Mint)
- Select Brand Infants' Gas Relief 20mg/0.3ml Drops
- Simethicone 125mg Chewable tablet
- Simethicone 125mg Oral capsule, liquid filled
- Simethicone 180mg Oral capsule, liquid filled
- Simethicone 20mg/0.3mL Oral drops, suspension
- Simethicone 80mg Chewable tablet
- Simethicone 80mg/10mL, Magnesium Hydroxide 800mg/10mL, Aluminum Hydroxide 800mg/10mL Oral suspension
- Simethicone Bulk liquid
- Teeny Tummy Infant Gas Relief 20mg/0.3mL Drops (Strawberry)
- Today's Health Gas Relief 125mg Extra Strength Softgel
- Top Care Gas Relief 125mg Extra Strength Softgel
- Top Care Infants' Gas Relief 20mg/0.3ml Drops

- TopCare Gas Relief Ultra Strength 180mg Softgel
- up & up Infants' Gas Relief Dye Free 20mg/0.3mL Drops
- Walgreens Antacid + Anti-Gas 800mg-800mg-80mg/10mL Maximum Strength Liquid (Classic)
- Walgreens Gas Relief 125mg Chewable Tablet
- Walgreens Gas Relief 125mg Chewable Tablet (Cherry Creme)
- Walgreens Gas Relief 125mg Extra Strength Softgel
- Walgreens Gas Relief 125mg Extra Strength Chewable Tablet (Cherry)
- Walgreens Gas Relief 125mg Extra Strength Chewable Tablet (Peppermint Creme)
- Walgreens Gas Relief 180mg Ultra Strength Softgel
- Walgreens Gas Relief Extra Strength 125mg Softgel
- Walgreens Gas Relief Ultra Strength 180mg Softgel
- Walgreens Infant Gas Relief 20mg/0.3mL Drops
- Walgreens Infants' Gas Relief 20mg/0.3ml Drops

## Dosage Adjustment Guidelines

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### Hepatic Impairment

No dosage adjustments are needed.

### Renal Impairment

No dosage adjustments are needed.

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