

# Simethicone (Pediatric and Neonatal Lexi-Drugs)

## Pronunciation

(syə METH i kone)

## Brand Names: US

FT Gas Relief Extra Strength [OTC]; FT Gas Relief Infants [OTC]; FT Gas Relief Ultra Strength [OTC]; FT Gas Relief [OTC]; Gas Relief Extra Strength [OTC]; Gas Relief Infants [OTC]; Gas Relief [OTC]; Gas-X Childrens [OTC]; Gas-X Extra Strength [OTC]; Gas-X Infant Drops [OTC]; Gas-X Maximum Strength [OTC]; Gas-X Ultra Strength [OTC]; Heartland Gas Relief [OTC]; Infants Gas Relief [OTC]; Mi-Acid Gas Relief [OTC] [DSC]; Mylicon Infants Gas Relief [OTC]; Phazyme Maximum Strength [OTC]; Phazyme Ultra Strength [OTC]; Phazyme [OTC]; Simethicone Drops Infants [OTC]; Simethicone Ultra Strength [OTC]; Teeny Tummy Gas Relief Drops [OTC]

## Therapeutic Category

Antiflatulent

## Dosing: Neonatal

### Gas pain/GI discomfort

**Gas pain/GI discomfort:** Neonate (including newborn): Oral: Oral drops/solution (20 mg/0.3 mL): 0.3 mL 4 times daily as needed after meals and at bedtime; do not exceed 12 doses/24 hours; maximum daily dose: 240 mg/24 hours

## Dosing: Pediatric

**Note:** Refer to product specific labeling for approved pediatric ages.

### Gas pain/GI discomfort

#### Gas pain/GI discomfort:

Infants and Children <2 years weighing <10.9 kg: Oral: 20 mg 4 times daily as needed after meals and at bedtime. Maximum daily dose: 240 mg/24 hours

Children <2 years weighing ≥10.9 kg and Children ≥2 to <12 years: Oral: 40 mg 4 times daily as needed after meals and at bedtime. Maximum daily dose: 480 mg/24 hours

Children ≥12 years and Adolescents: 40 to 125 mg 4 times daily as needed after meals and at bedtime; with some formulations, may administer a single 250 mg dose if needed; maximum daily dose: 500 mg/24 hours

## Dosing: Altered Kidney Function: Pediatric

There are no dosage adjustments provided in manufacturer's labeling; dosage adjustment unlikely due to the drug not being systemically absorbed.

## Dosing: Altered Liver Function: Pediatric

There are no dosage adjustments provided in manufacturer's labeling; dosage adjustment unlikely due to the drug not being systemically absorbed.

## Dosing: Adult

### Gas retention

**Gas retention:** Oral: Usual dose: 40 to 125 mg 4 times daily as needed after meals and at bedtime; may administer single doses of up to 160 to 500 mg after meals or at bedtime, not to exceed a maximum daily dose of 500 mg/day

## Dosing: Altered Kidney Function: Adult

The renal dosing recommendations are based upon the best available evidence and clinical expertise. Senior Editorial Team: Bruce Mueller, PharmD, FCCP, FASN, FNKF; Jason A. Roberts, PhD, BPharm (Hons), B App Sc, FSHP, FISAC; Michael Heung, MD, MS.

**Altered kidney function:** No dosage adjustment necessary for any degree of kidney impairment (no systemic absorption) (<sup>Ref</sup>).

**Hemodialysis, intermittent (thrice weekly):** No dosage adjustment necessary (no systemic absorption) (<sup>Ref</sup>).

**Peritoneal dialysis:** No dosage adjustment necessary (no systemic absorption) (<sup>Ref</sup>).

**CRRT:** No dosage adjustment necessary (no systemic absorption) (<sup>Ref</sup>).

**PIRRT (eg, sustained, low-efficiency diafiltration):** No dosage adjustment necessary (no systemic absorption) (<sup>Ref</sup>).

## Dosing: Altered Liver Function: Adult

There is no dosage adjustment provided in the manufacturer's labeling. However, dosage adjustment unlikely due to the drug not being systemically absorbed.

## Use

Relief of pressure, bloating, fullness, and discomfort of gastrointestinal gas (FDA approved in all ages); **Note:** OTC: Approved ages and uses for generic products may vary; consult labeling for specific information.

## Administration: Pediatric

Oral:

Chewable tablet: Chew thoroughly and swallow.

Suspension (drops): Shake well before using. Fill enclosed dropper to recommended dosage level and dispense slowly in mouth towards inner cheek. May mix with 30 mL water, infant formula, or other liquids.

Strips: Allow to dissolve on tongue.

## Administration: Adult

Oral: Chewable tablet: Chew thoroughly and swallow

Oral suspension (drops): Shake well before using; may mix with 30 mL water or other liquids.

Oral strips: Allow to dissolve on tongue.

## Storage/Stability

Store at 20°C to 25°C (68°F to 77°F). Protect from moisture. Avoid high humidity and excessive heat.

Oral suspension: Do not freeze.

## Patient Counseling Points

### What is this drug used for?

- It is used to ease too much gas in the GI (gastrointestinal) tract.

**WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:**

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.

**Note:** This is not a comprehensive list of all side effects. Talk to your doctor if you have questions.

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## Medication Safety Issues

### Sound-alike/look-alike issues:

Simethicone may be confused with cimetidine

Mylanta may be confused with Mynatal

Mylicon may be confused with Modicon, Myleran

## Warnings/Precautions

### *Dosage form specific issues:*

- Benzyl alcohol and derivatives: Some dosage forms may contain sodium benzoate/benzoic acid; benzoic acid (benzoate) is a metabolite of benzyl alcohol; large amounts of benzyl alcohol ( $\geq 99$  mg/kg/day) have been associated with a potentially fatal toxicity ("gasping syndrome") in neonates; the "gasping syndrome" consists of metabolic acidosis, respiratory distress, gasping respirations, CNS dysfunction (including convulsions, intracranial hemorrhage), hypotension, and cardiovascular collapse (AAP ["Inactive" 1997]; CDC, 1982); some data suggests that benzoate displaces bilirubin from protein binding sites (Ahlfors, 2001); avoid or use dosage forms containing benzyl alcohol derivative with caution in neonates. See manufacturer's labeling.

## Pregnancy Considerations

Simethicone is physiologically inert and not absorbed systemically following oral administration (Danhof 1974).

## Breastfeeding Considerations

Simethicone is physiologically inert and not absorbed systemically following oral administration (Danhof 1974). Due to lack of systemic absorption, simethicone is not expected to be present in breast milk (Hagemann 1998).

## Briggs' Drugs in Pregnancy & Lactation

- [Simethicone](#)

## Adverse Reactions

No data reported

## Drug Interactions: Metabolism/Transport Effects

None known.

## Drug Interactions

### [Open Interactions](#)

**Note:** Interacting drugs may **not be individually listed below** if they are part of a group interaction (eg, individual drugs within "CYP3A4 Inducers [Strong]" are NOT listed). For a complete list of drug interactions by individual drug name and detailed management recommendations, use the drug interactions program by clicking on the "Open Interactions" button above.

There are no known significant interactions.

## Food Interactions

Avoid carbonated beverages and gas-forming foods.

## Dosage Forms: US

Excipient information presented when available (limited, particularly for generics); consult specific product labeling. [DSC] = Discontinued product

Capsule, Oral:

FT Gas Relief Extra Strength: 125 mg [contains fd&c blue #1 (brilliant blue), fd&c red #40 (allura red ac dye), quinoline yellow (d&c yellow #10)]

FT Gas Relief Ultra Strength: 180 mg [contains fd&c red #40 (allura red ac dye), fd&c yellow #6 (sunset yellow)]

Gas Relief Extra Strength: 125 mg [contains fd&c blue #1 (brilliant blue), fd&c red #40 (allura red ac dye), quinoline yellow (d&c yellow #10)]

Gas-X Extra Strength: 125 mg [contains fd&c blue #1 (brilliant blue), fd&c red #40 (allura red ac dye), quinoline yellow (d&c yellow #10)]

Gas-X Maximum Strength: 250 mg [contains fd&c blue #1 (brilliant blue)]

Gas-X Ultra Strength: 180 mg [contains fd&c yellow #6 (sunset yellow)]

Phazyme Maximum Strength: 250 mg [contains fd&c blue #1 (brilliant blue)]

Phazyme Ultra Strength: 180 mg [contains fd&c red #40 (allura red ac dye), fd&c yellow #6 (sunset yellow)]

Phazyme Ultra Strength: 180 mg [contains fd&c yellow #6 (sunset yellow)]

Simethicone Ultra Strength: 180 mg [DSC] [contains fd&c red #40 (allura red ac dye), fd&c yellow #6 (sunset yellow)]

Simethicone Ultra Strength: 180 mg [contains fd&c yellow #6 (sunset yellow)]

Generic: 125 mg, 180 mg

#### Liquid, Oral:

Gas-X Infant Drops: 20 mg/0.3 mL (30 mL) [alcohol free, no artificial color(s), no artificial flavor(s), saccharin free; contains polyethylene glycol (macrogol), sodium benzoate]

#### Strip, Oral:

Gas-X Childrens: 40 mg (16 ea) [contains alcohol, usp, fd&c red #40 (allura red ac dye); sweet cinnamon flavor]

Gas-X Extra Strength: 62.5 mg (18 ea) [contains alcohol, usp, fd&c red #40 (allura red ac dye)]

#### Suspension, Oral:

FT Gas Relief Infants: 20 mg/0.3 mL (30 mL) [alcohol free, saccharin free; contains benzoic acid]

Gas Relief Infants: 20 mg/0.3 mL (30 mL) [dye free; contains sodium benzoate]

Infants Gas Relief: 20 mg/0.3 mL (30 mL [DSC]) [contains sodium benzoate]

Infants Gas Relief: 20 mg/0.3 mL (30 mL) [dye free; contains sodium benzoate]

Mylicon Infants Gas Relief: 20 mg/0.3 mL (15 mL) [contains d&c red #22 (eosine), sodium benzoate]

Mylicon Infants Gas Relief: 20 mg/0.3 mL (30 mL) [alcohol free, dye free, gluten free, saccharin free; contains sodium benzoate]

Simethicone Drops Infants: 20 mg/0.3 mL (30 mL) [dye free, no artificial color(s), no artificial flavor(s), saccharin free; contains sodium benzoate]

Teeny Tummy Gas Relief Drops: 20 mg/0.3 mL (30 mL) [alcohol free, gluten free, no artificial color(s), no artificial flavor(s), paraben free; contains sodium benzoate]

Generic: 40 mg/0.6 mL (30 mL)

**Tablet Chewable, Oral:**

FT Gas Relief: 80 mg [contains corn starch]

FT Gas Relief Extra Strength: 125 mg

Gas Relief: 80 mg [peppermint flavor]

Gas Relief: 80 mg [contains corn starch]

Gas Relief: 80 mg [DSC] [lactose free]

Gas Relief Extra Strength: 125 mg

Gas Relief Extra Strength: 125 mg [DSC] [contains fd&c red #40(allura red ac)aluminum lake]

Gas Relief Extra Strength: 125 mg [lactose free; contains quinoline (d&c yellow #10) aluminum lake]

Gas-X Extra Strength: 125 mg [contains quinoline (d&c yellow #10) aluminum lake; peppermint creme flavor]

Gas-X Extra Strength: 125 mg [contains soy protein]

Gas-X Extra Strength: 125 mg [contains soy protein; cherry cream flavor]

Heartland Gas Relief: 80 mg [contains corn starch]

Mi-Acid Gas Relief: 80 mg [DSC]

Phazyme: 125 mg [cool mint flavor]

Generic: 80 mg, 125 mg

**Pricing: US**

**Capsules** (Gas-X Extra Strength Oral)

125 mg (per each): \$0.20

**Capsules** (Gas-X Maximum Strength Oral)

250 mg (per each): \$0.54

**Capsules** (Gas-X Ultra Strength Oral)

180 mg (per each): \$0.31

**Capsules** (Phazyme Maximum Strength Oral)

250 mg (per each): \$0.43

**Capsules** (Phazyme Ultra Strength Oral)

180 mg (per each): \$0.24

**Capsules** (Simethicone Oral)

125 mg (per each): \$0.15

180 mg (per each): \$0.17

**Chewable** (Gas-X Extra Strength Oral)

125 mg (per each): \$0.41

**Chewable** (Phazyme Oral)

125 mg (per each): \$0.19

**Chewable** (Simethicone Oral)

80 mg (per each): \$0.02 - \$0.24

125 mg (per each): \$0.06

**Liquid** (Gas-X Infant Drops Oral)

20 mg/0.3 mL (per mL): \$0.28

**Strip** (Gas-X Childrens Oral)

40 mg (per each): \$0.34

**Strip** (Gas-X Extra Strength Oral)

62.5 mg (per each): \$0.24

**Suspension** (Mylicon Infants Gas Relief Oral)

20 mg/0.3 mL (per mL): \$0.35

**Suspension** (Simethicone Oral)

40 mg/0.6 mL (per mL): \$0.24

**Tablets** (Bicarsim Oral)

80 mg (per each): \$0.33

**Disclaimer:** A representative AWP (Average Wholesale Price) price or price range is provided as reference price only. A range is provided when more than one manufacturer's AWP price is available and uses the low and high price reported by the manufacturers to determine the range. The pricing data should be used for benchmarking purposes only, and as such should not be used alone to set or adjudicate any prices for reimbursement or purchasing functions or considered to be an exact price for a single product and/or manufacturer. Medi-Span expressly disclaims all warranties of any kind or nature, whether express or implied, and assumes no liability with respect to accuracy of price or price range data published in its solutions. In no event shall Medi-Span be liable for special, indirect, incidental, or consequential damages arising from use of price or price range data. Pricing data is updated monthly.



## Generic Availability (US)

May be product dependent

## Mechanism of Action

Decreases the surface tension of gas bubbles thereby disperses and prevents gas pockets in the GI system

## Pharmacokinetics (Adult Data Unless Noted)

Absorption: Not systemically absorbed (Danhof 1974; Hagemann 1998).

Excretion: Feces.

## Index Terms

Activated Methylpolysiloxane

## Brand Names: International

**Find brand name(s) by country (for United States and Canada see separate Brand Names sections)**

🔍 Enter a Country or Country Code

For country code abbreviations (  [show table](#) )

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