

**COLIC CALM- carbo vegetabilis, carum carvi, chamomilla, foeniculum vulgare, melissa officinalis, mentha piperita, prunus spinosa, zingiber officinale liquid CalmCo LLC**

*Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.*

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**Colic Calm**

**Active ingredients:**

|                     |    |
|---------------------|----|
| Carbo Vegetabilis   | 1X |
| Carum Carvi         | 3X |
| Chamomilla          | 3X |
| Foeniculum Vulgare  | 3X |
| Melissa Officinalis | 3X |
| Mentha Piperita     | 3X |
| Prunus Spinosa      | 3X |
| Zingiber Officinale | 3X |

**Purpose**

gas relief, upset stomach

digestive aid

irritability, hiccups

gas relief

irritability, restlessness

bloating, colic

upset stomach, colic

digestive aid

**Uses:**

Temporarily relieves the symptoms of infant:

**colic • gas • reflux • upset stomach • bloating • hiccups**

\*Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.

**Warnings:**

- **Do not use** if protective wrap on oral dispenser is broken or missing.
- **Stop use and consult a doctor if** symptoms last more than 7 days or inflammation,

fever or infection occurs.

- As with all medications, it is important to ensure that your child's medical professional is aware of the use of this product.
- As our product is black, a temporarily, harmless, darkening of the stool may occur.
- May stain fabric; protect clothing and furniture.

**Keep out of reach of children:**

In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions:**

**Weight Dose**

Under 20 lbs. 1/4 teaspoon (1.25 mL)

Over 20 lbs. 1/2 teaspoon (2.5 mL)

- Remove protective wrap from oral dispenser.
- Shake well before use.
- Fill enclosed dispenser up to indicated dose level and dispense liquid slowly (drop by drop) into mouth, between cheek and gums.
- If needed, repeat every 60 minutes for up to 3 doses. Do not exceed 4 full doses in 24 hours.
- Recap bottle and clean dispenser after use.
- Discard remaining product after 3 weeks.

**Other Information:**

- Please note: Sleep may follow naturally after relief.
- Store at room temperature, out of direct sunlight.

**Inactive ingredients:**

Benzoic acid, citric acid (anhydrous), glycerin, potassium citrate, potassium sorbate, purified water, xanthan gum, xylitol

**Questions:**

**Questions or Comments?**

Call 941-203-4590

Visit [www.coliccalm.com](http://www.coliccalm.com)

**Patient information:**

Relief. Pure & Simple. Thank you for choosing Colic Calm, the first homeopathic gripe water for the treatment of colic, gas and upset stomach. Our product has been used by more than a million babies...and counting. In fact, it is recommended by pediatricians, natural health care practitioners, and pharmacists.

Colic Calm is:

- Safe, gentle and effective
- Non-habit forming
- A smart alternative to conventional drugs

What is the purpose of Colic Calm?

Colic Calm homeopathic medicine provides relief for discomfort from gas, colic, upset stomach, and even hiccups in infants. Importantly, Colic Calm is made according to Good Manufacturing Practices (GMP) for over-the-counter homeopathic medicines.

Is Colic Calm safe for my baby?

Colic Calm is a combination of eight homeopathic remedies, each of which has a long history of safe use. The proprietary formula is non-habit forming and does NOT contain sugar, sodium bicarbonate, simethicone, herbal oils, soy, dairy, wheat, gluten, animal products, artificial flavors or colors.

What makes Colic Calm different from other colic preparations?

The active ingredients in Colic Calm provide multi-symptom relief to quickly soothe baby's digestive system. According to the principles of homeopathy, each dose gently stimulates the body's ability to heal itself, as opposed to merely suppressing symptoms.

How long does Colic Calm take to work?

Most babies experience relief with their first dose of Colic Calm. However, some may take longer before showing noticeable improvement. We recommend giving Colic Calm up to one week to fully work its wonders. Keep in mind that many babies simply have trouble calming down once the crying cycle has begun, so it is recommended to administer Colic Calm at the first signs of discomfort.

We encourage you to email us at [customercare@coliccalm.com](mailto:customercare@coliccalm.com) or call us at (941) 203-4590 for helpful customized suggestions that can make a difference.

What are the directions for use?

At the first signs of digestive discomfort, shake glass bottle to obtain a uniform dark mixture. Fill enclosed oral dispenser and dispense liquid slowly, drop-by-drop, into mouth, between cheek and gums. Do not dispense faster than baby can comfortably swallow. If needed, repeat once every 60 minutes for up to 3 doses, or as directed by a physician. Do not exceed the equivalent of 4 full doses for the appropriate weight category per day. Carefully recap bottle, clean oral dispenser and let air-dry after each use.

What if my baby spits up Colic Calm?

Some spitting up is normal. One factor is temperature. Some babies' stomachs are sensitive to cooler liquids, so Colic Calm at room temperature could be unsettling. Colic Calm may be added to a small amount (1 or 2 ounces) of warmed formula or pumped breast milk to raise temperature and change the taste and texture back to something familiar. Every baby is different, so a little trial and error is sometimes needed. It is best to avoid giving Colic Calm immediately after feeding if baby's stomach is full, as spit-up may occur from the added pressure.

Can my baby take other medications while using Colic Calm?

As with all medications, it is important to ensure that your doctor is aware of the use of this product. Always check with your doctor if your baby is taking other medications or has been treated for health concerns.

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Not FDA evaluated.

If other medications are being used, allow a two-hour window between the other medication and Colic Calm, so that the effects of the other medication are not lessened.

Does Colic Calm have any side effects?

There are no known contraindications to any of the active ingredients in Colic Calm. However, it is always advised that you check with your doctor before introducing any product.

You may notice a temporary, harmless, darkening of the stool. This occurs because Colic Calm uses a form of carbon called Carbo Vegetabilis (vegetable charcoal). This pure, naturally-derived, non-carcinogenic vegetable charcoal makes Colic Calm black in color. Vegetable charcoal does not enter the bloodstream, and passes out of the body naturally and easily, along with the gas and toxins it has collected on its journey through the digestive tract.

What is the best way to get out stains?

Colic Calm's rich dark color is as Mother Nature intended, without any "pretty" coloring to alter its purity and efficacy. While the microfine particles of vegetable charcoal do not contain any dye, they can get lodged in fabrics and may require gentle manipulation to loosen. This is why we have included a stain warning on bottle and box.

We find that stains lift out easily with most spray stain removers. It is best to treat stains promptly. For stubborn stains, try pre-spotting with dishwashing liquid before washing. Many parents keep bibs and rags handy, so that stain removal doesn't become an issue.

Can Colic Calm be used for anything other than colic?

Yes. Colic Calm is helpful in easing pain associated with stomach upset. Many toddlers and older children benefit from stomach ache relief with Colic Calm. Colic Calm can also provide relief for flatulence and bloating from gas. In addition, a great number of parents swear by Colic Calm for effective treatment of hiccups.

How long should each bottle last?

Each bottle contains (47) ¼ teaspoon (1.25 ml) doses for babies under 20 lbs. or (24) ½ teaspoon (2.5 ml) doses for those over 20 lbs. Some children require more doses than others, depending on the frequency of their symptoms. Discard bottle within 8 weeks after opening.

How do I store Colic Calm?

This product should be stored at room temperature, out of direct sunlight. Because there is no need for refrigeration, Colic Calm is also ideal for traveling away from home.

Why does my baby sleep soundly and longer after taking Colic Calm?

Peaceful sleep often follows naturally after relief. There are no narcotic, sedative or habit-forming ingredients in Colic Calm.

What is "colic"?

Colic is defined as inconsolable crying that lasts for more than 3 hours per day for at least 3 days per week. Colic is a self-limiting condition that typically resolves by 3-4 months of age. Most experts point to gastrointestinal discomfort as the cause, due to the immaturity of a baby's digestive system:

- i. "Intestinal hyperperistalsis is one part of the clinical picture in infantile colic:• - Motilin, Vasoactive Intestinal Peptide and Gastrin in Infantile Colic by L. Lothe, MD, S. A. Ivarsson, MD, and T. Lindberg
- ii. "various factors act in tandem, leading to disturbances in infant gastrointestinal motility that manifests clinically as colic:' - Is colic a gastrointestinal disorder? by Gupta,

Sandeep K., M.D.

iii. "Observation of colicky infants has suggested a gastrointestinal origin for this discomfort." - Efficacy of herbal tea preparation in infantile colic by Zvi Weizman, MD, Soliman Alkrinawi, M.D., Dan Goldfarb, M.D., and Chaim Bitran, M.D

\*\* All active ingredients are derived from natural sources. Homeopathy and Dilutions  
The homeopathic ingredients in Colic Calm are diluted either to 1X or 3X potency. A 1X dilution is obtained by mixing 1 part of the medicinal ingredient with 9 parts of a neutral diluting agent then vigorously shaking the solution (succussion). The 3X is obtained by repeating this dilution and succussion process 3 times. Six of the eight active ingredients in Colic Calm operate according to homeopathic principles at a 3X potency, 1 part per 1,000, or 0.1%. This level of dilution is found in some non-homeopathic pharmaceuticals in use today. Drugs such as Ergocalciferol, are much more diluted than 1 part per 1000. Unlike most drugs, homeopathic products are not subject to pre-market approval by the Food and Drug Administration (FDA) and are not reviewed by the FDA.

Activated Charcoal

Colic Calm derives its rich black color from Carbo Vegetabilis 1X (also known as activated charcoal or medicinal carbon). A 1X dilution is a dilution of one part per 10. The activated charcoal in Colic Calm is prepared according to HPUS methods. Charcoal has been used safely in medicinal applications for thousands of years.

The activated charcoal in Colic Calm relieves the bloating and abdominal discomfort attributable to gaseousness in colicky babies. Charcoal's efficacy in adsorbing gases and toxins in the digestive system has been established in several studies and medical texts including:

Each dose of Colic Calm contains amounts of activated charcoal corresponding to the amounts used in these efficacy studies, adjusting for the size of the baby.

i. "a child's drug dose may be weight (in kg) times 2% of an adult dose" - Calculation of drug dosage and body surface area of children. J A Lack and ME Stuart-Taylor

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Not FDA evaluated.

Does Colic Calm work?

While no product can claim to work for everyone, Colic Calm does have an impressive track record. Visit our website [www.coliccalm.com/video/](http://www.coliccalm.com/video/) to view "Seeing is Believing" videos of parents using our products with immediate results. Also, check out hundreds of five star reviews on [amazon.com](http://amazon.com) and read "One Mom's Story" customer interviews at [journal.coliccalm.com](http://journal.coliccalm.com).

Many pediatricians and medical professionals also recommend our products:

"Colic Calm incorporates natural ingredients to reduce colic symptoms ... I frequently recommend Colic Calm for my patients because it provides safe, natural relief for symptoms of colic. Our parents' feedback has been tremendously positive and our patients' symptoms have improved in almost all instances."

- Steven E. Rahman, M.D., Pediatrician, Lake Worth, Florida

"Colic Calm has really been an excellent treatment for my patients with colic. I have mothers giving me positive feedback on how wonderful Colic Calm has been in relieving colic symptoms in infants of all ages. I even used the product on my own grandson with great results!"

- Roger Mendoza, M.D., Pediatrician, Beaumont, Texas

"Colic Calm had a soothing effect on my baby... I've not seen anything so amazing as Colic Calm. What a valuable breakthrough."

- Geneva Lejeune, M.D., Pediatrician, Shreveport, Louisiana

"Excellent product. We used everything...gripe water, gas drops and other

homeopathic treatments. This is the ONLY thing that worked for my daughter's colic."

- Shahreen Hussain-Malik, M.D., Pediatrician, Phoenix, Arizona

We fully stand behind our product with our money-back guarantee, but realize that not every baby will experience relief from Colic Calm. We encourage you to contact our Colic Calm Customer Care Team for customized suggestions that can make a difference. Cease using the product if you do not see noticeable improvement within one week. Your baby simply may not have common "colic"; or the condition may be one that Colic Calm cannot treat. Contact your local point-of-purchase retailer for an immediate refund. If your retailer does not provide a refund, contact us for a full refund of the purchase price. Just send us a copy of the receipt within 30 days of purchase along with the unused portion and we will refund your purchase and shipping costs. Please visit <https://www.coliccalm.com/guarantee.htm> for full details on our refund policy. Refunds available to US customers only.

Do not use Colic Calm to treat other medical conditions not indicated on the product packaging. Colic Calm should not be used to treat chronic conditions, conditions that are not self-limiting or conditions that require a doctor's diagnosis. Conditions unrelated to colic that may cause a baby to exhibit discomfort include, but are not limited to, lactose intolerance, cow's milk allergy, gastrointestinal infections or infections of any kind, allergies or sensitivities. Always consult your doctor concerning your baby's health condition and the use of this or any other medicine.

\*\* All active ingredients are derived from natural sources.

- i. "Activated charcoal also significantly reduced the number of volunteers having abdominal symptoms and the symptom score. Our data clearly indicates that activated charcoal is an effective anti-gas medication. Simethicone, also commonly prescribed for gaseousness, was not found to be effective:" - Activated Charcoal, Simethicone, and Intestinal Gas: A Double - Blind Study by Naresh K. Jain, M.D., Vijay P. Patel, M.D., and C. S. Pitchumoni, M.D.
- ii. "These experiments showed that orally administered activated charcoal was effective in preventing the large increase in the number of flatus events and increased breath hydrogen concentrations that normally occur following a gas-producing meal:" - Effects of Orally Administered Activated Charcoal on Intestinal Gas by R.J. Hall, E. Thompson, and A. Strother.
- iii. "Symptoms of bloating and abdominal cramps attributable to gaseousness were also significantly reduced in both groups by activated charcoal." - Efficacy of Activated Charcoal in Reducing Intestinal Gas: a Double - Blind Clinical Trial by Jain NK, M.D., Patel VP, M.D., Pitchumoni CS, M.D.
- iv. "The use of activated charcoal for adsorbing intestinal gas has been effective in healthy subjects" - Gastrointestinal Gas. Fardy J, Sullivan S.
- v. "Activated charcoal or prokinetic agents also can be effective options in some patients for intestinal gas:" - Intestinal Gas by Fink RN, Lembo AJ.
- vi. "The improvement was still evident 2 months after the end of treatment." - Efficacy of an activated charcoal / simethicone combination in dyspeptic syndrome: results of a randomized prospective study in general practice. Lecuyer M, Cousin T, Monnot MN, Coffin B.

**Package Label Display: 73282-0001-2**



**Package Label Display: 73282-0001-3**

### Drug Facts

#### Active Ingredients

Carbo Vegetabilis 1X, Carum Carvi 3X, Chamomilla 3X, Foeniculum Vulgare 3X, Melissa Officinalis 3X, Mentha Piperita 3X, Prunus Spinosa 3X, Zingiber Officinale 3X

#### Uses

Temporarily relieves the symptoms of infant:  
**colic • gas • reflux • upset stomach • bloating • hiccups**

#### Warnings

• **Tamper Evident: do not use** if carton is open, or wrap on oral dispenser is broken or missing. • **Stop use and consult a doctor if** symptoms last more than 7 days or inflammation, fever, or infection occurs. • As with all medications, it is important to ensure that your child's medical professional is aware of the use of this product. • As our product is black, a temporary harmless darkening of stool may occur. • May stain fabric; take care to protect clothing and furniture. • **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

#### Questions or Comments?

Call 941-203-4590 visit [www.coliccalm.com](http://www.coliccalm.com)

# Colic Calm™

Liquid Homeopathic Medicine

For symptomatic relief of infant

## Colic, Gas & Reflux

CalmCo.

1.7 Fl. Oz. (50 ml)  
20 - 40 doses

### Drug Facts (continued)

#### Directions

| Weight              | Dose                 |
|---------------------|----------------------|
| Under 20 lbs (9 kg) | ¼ teaspoon (1.25 ml) |
| Over 20 lbs (9 kg)  | ½ teaspoon (2.5 ml)  |

• Remove protective wrap from oral dispenser  
• Shake well before use • Fill enclosed dispenser up to indicated dose level and dispense liquid slowly (drop by drop) into mouth, between cheek and gums • If needed, repeat every 60 minutes for up to 3 doses. Do not exceed 4 full doses in 24 hours • Recap bottle and clean dispenser after use • Discard remaining product after 3 weeks.

#### Other Information

• Please note: sleep may follow naturally after relief • Store at room temperature, out of direct sunlight

#### Inactive Ingredients

Benzoic acid, citric acid (anhydrous), glycerin, potassium citrate, potassium sorbate, purified water, xanthan gum, xylitol

Made in South Africa  
Distributed by CalmCo LLC,  
Sarasota FL 34240





## COLIC CALM

carbo vegetabilis, carum carvi, chamomilla, foeniculum vulgare, melissa officinalis, mentha piperita, prunus spinosa, zingiber officinale liquid

### Product Information

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:73282-0001 |
| <b>Route of Administration</b> | ORAL           |                           |                |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength  | Strength |
|---|--------------------|----------|
| ACTIVATED CHARCOAL (UNII: 2P3VWU3H10) (ACTIVATED CHARCOAL - | ACTIVATED CHARCOAL | 1 [hp_X] |

|   |                           |                     |
|---|---------------------------|---------------------|
| UNII:2P3VWU3H10)  | ACTIVATED CHARCOAL        | in 1 mL             |
| <b>CARAWAY SEED</b> (UNII: W2FH8O2BBE) (CARAWAY SEED - UNII:W2FH8O2BBE)                           | CARAWAY SEED              | 3 [hp_X]<br>in 1 mL |
| <b>CHAMOMILE</b> (UNII: FGL3685T2X) (CHAMOMILE - UNII:FGL3685T2X)                                 | CHAMOMILE                 | 3 [hp_X]<br>in 1 mL |
| <b>FENNEL SEED</b> (UNII: G3QC02NIE6) (FENNEL SEED - UNII:G3QC02NIE6)                             | FENNEL SEED               | 3 [hp_X]<br>in 1 mL |
| <b>MELISSA OFFICINALIS</b> (UNII: YF70189L0N) (MELISSA OFFICINALIS - UNII:YF70189L0N)             | MELISSA OFFICINALIS       | 3 [hp_X]<br>in 1 mL |
| <b>MENTHA PIPERITA</b> (UNII: 79M2M2UDA9) (MENTHA PIPERITA - UNII:79M2M2UDA9)                     | MENTHA PIPERITA           | 3 [hp_X]<br>in 1 mL |
| <b>PRUNUS SPINOSA FLOWER BUD</b> (UNII: 53Y84VPS2W) (PRUNUS SPINOSA FLOWER BUD - UNII:53Y84VPS2W) | PRUNUS SPINOSA FLOWER BUD | 3 [hp_X]<br>in 1 mL |
| <b>GINGER</b> (UNII: C5529G5JPQ) (GINGER - UNII:C5529G5JPQ)                                       | GINGER                    | 3 [hp_X]<br>in 1 mL |

### Inactive Ingredients

| Ingredient Name                                 | Strength |
|---|----------|
| <b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL) |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)              |          |
| <b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)          |          |
| <b>POTASSIUM CITRATE</b> (UNII: EE90ONI6FF)     |          |
| <b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)     |          |
| <b>WATER</b> (UNII: 059QF0KO0R)                 |          |
| <b>XANTHAN GUM</b> (UNII: TTV12P4NEE)           |          |
| <b>XYLITOL</b> (UNII: VCQ006KQ1E)               |          |

### Packaging

| # | Item Code        | Package Description   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:73282-0001-1 | 59 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product | 08/30/2019           | 03/31/2025         |
| 2 | NDC:73282-0001-2 | 1 in 1 CARTON   | 04/01/2023           | 03/31/2025         |
| 2 |                  | 59 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product |                      |                    |
| 3 | NDC:73282-0001-3 | 1 in 1 CARTON   | 04/01/2023           | 03/31/2025         |
| 3 |                  | 50 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product |                      |                    |

### Marketing Information

| Marketing Category     | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|------------------------|--|----------------------|--------------------|
| unapproved homeopathic |  | 08/30/2019           | 03/31/2025         |

