

COLIC CALM PLUS- aloe, asafoetida, carbo vegetabilis, carum carvi, chamomilla, cinchona officinalis, foeniculum vulgare, magnesia phosphorica, 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.

Colic Calm Plus

Active ingredients:

Aloe	8X
Asafoetida	3X
Carbo Vegetabilis	1X
Carum Carvi	3X
Chamomilla	3X
Cinchona Officinalis	3X
Foeniculum Vulgare	3X
Magnesia Phosphorica	8X
Melissa Officinalis	3X
Mentha Piperita	3X
Prunus Spinosa	3X
Zingiber Officinale	3X

Purpose

gas relief, bloating

gas relief, bloating

gas relief, upset stomach

digestive aid

irritability, hiccups

bloating

gas relief

colic, 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.
- 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 (9kg)	1/4 teaspoon (1.25 ml)
Over 20 lbs (9kg)	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

Patient information:

Natural Relief When It's Needed Most*

Thank you for choosing Colic Calm Plus, the first homeopathic gripe water for the treatment of colic, gas and upset stomach. While original Colic Calm combines eight homeopathic ingredients, Colic Calm PLUS includes four additional homeopathic remedies. It is recommended by pediatricians, natural health care practitioners, and pharmacists.

Colic Calm PLUS® is:

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

What is the purpose of Colic Calm PLUS?

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

Is Colic Calm PLUS safe for my baby?

Colic Calm PLUS is a combination of twelve 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, yeast, animal products, artificial flavors or colors.

What makes Colic Calm PLUS different from other colic preparations?

The active ingredients in Colic Calm PLUS 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 PLUS take to work?

Most babies experience relief with their first dose of Colic Calm PLUS. However, some may take longer before showing noticeable improvement.

We recommend giving Colic Calm PLUS 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 PLUS at the first signs of discomfort.

We encourage you to email us at 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 PLUS?

Some spitting up is normal. One factor is temperature. Some babies' stomachs are sensitive to cooler liquids, so Colic Calm PLUS at room temperature could be unsettling. Colic Calm PLUS 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 PLUS immediately after feeding if baby's stomach is full, as spit-up may occur from the added pressure.

* All active ingredients are derived from natural sources.

Can my baby take other medications while using Colic Calm PLUS?

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

Does Colic Calm PLUS have any side effects?

There are no known contraindications to any of the active ingredients in Colic Calm PLUS. 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 Plus uses a form of carbon called Carbo Vegetabilis (vegetable charcoal). This pure, naturally-derived, non-carcinogenic vegetable charcoal makes Colic Calm PLUS 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?

The rich dark color of Colic Calm PLUS 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 PLUS be used for anything other than colic?

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

How do I store Colic Calm PLUS?

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

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

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

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 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.

** These statements are based upon traditional homeopathic practice. They have not been reviewed by the Food and Drug Administration.

Frequently Asked Questions

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.

Homeopathy and Dilutions

The homeopathic ingredients in Colic Calm PLUS are diluted either to 1X, 3X or 8X 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. Nine of the twelve active ingredients in Colic Calm PLUS 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. The FDA has not evaluated this product.

Activated Charcoal

Colic Calm PLUS 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 PLUS is prepared according to HPUS methods. Charcoal has been used safely in medicinal applications for thousands of years. The activated charcoal in Colic Calm PLUS 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:

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.

i. "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.

Each dose of Colic Calm PLUS 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

* All active ingredients are derived from natural sources.

Does Colic Calm Plus 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/ 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 and read "One Mom's Story" customer interviews at journal.coliccalm.com.

Many pediatricians and medical professionals also recommend our products:

"We have been providing Colic Calm Plus to our patients at The Good Family Chiropractic Center for about a year now. We see a lot of pregnant women & babies in our office and they are always looking for natural remedies for colic, gas & reflux. Almost everyone that has used this product for their babies has had a positive result. We only use natural products in our office so we proudly display Colic Calm because it Homeopathic, with no side effects! Thank you for your dedication to a safe & effective product for our patients."

- Drs. Michael & Katie Sarnoff, The Good Family Chiropractic Center, New Jersey
"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

We fully stand behind our product with our money-back guarantee, but realize that not every baby will experience relief from Colic Calm PLUS. We encourage you to contact our Colic Calm PLUS 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 PLUS 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 PLUS to treat other medical conditions not indicated on the product packaging. Colic Calm PLUS 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.

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Learn More About Colic PLUS®

Visit coliccalm.com or contact us directly:

Email customercare@coliccalm.com

Phone (941) 203-4590

CCP-IN-001-02

Package Label Display: 73282-0003-2



COLIC CALM PLUS

aloe, asafoetida, carbo vegetabilis, carum carvi, chamomilla, cinchona officinalis, foeniculum vulgare, magnesia phosphorica, melissa officinalis, mentha piperita, prunus spinosa, zingiber officinale liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73282-0003
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALOE (UNII: V5VD430YW9) (ALOE - UNII:V5VD430YW9)	ALOE	8 [hp_X] in 1 mL
FERULA ASSA-FOETIDA RESIN (UNII: W9FZA51AS1) (ASAFETIDA - UNII:W9FZA51AS1)	FERULA ASSA-FOETIDA RESIN	3 [hp_X] in 1 mL
ACTIVATED CHARCOAL (UNII: 2P3VWU3H10) (ACTIVATED CHARCOAL -	ACTIVATED CHARCOAL	1 [hp_X]

UNII:2P3VWU3H10)	ACTIVATED CHARCOAL	in 1 mL
CARAWAY OIL (UNII: C2J9B08Q3I) (CARAWAY OIL - UNII:C2J9B08Q3I)	CARAWAY OIL	3 [hp_X] in 1 mL
CHAMOMILE (UNII: FGL3685T2X) (CHAMOMILE - UNII:FGL3685T2X)	CHAMOMILE	3 [hp_X] in 1 mL
CINCHONA OFFICINALIS BARK (UNII: S003A158SB) (CINCHONA OFFICINALIS BARK - UNII:S003A158SB)	CINCHONA OFFICINALIS BARK	3 [hp_X] in 1 mL
FENNEL SEED (UNII: G3QC02NIE6) (FENNEL SEED - UNII:G3QC02NIE6)	FENNEL SEED	3 [hp_X] in 1 mL
MAGNESIUM PHOSPHATE, DIBASIC TRIHYDRATE (UNII: HF539G9L3Q) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM PHOSPHATE, DIBASIC TRIHYDRATE	8 [hp_X] in 1 mL
MELISSA OFFICINALIS (UNII: YF70189L0N) (MELISSA OFFICINALIS - UNII:YF70189L0N)	MELISSA OFFICINALIS	3 [hp_X] in 1 mL
MENTHA PIPERITA (UNII: 79M2M2UDA9) (MENTHA PIPERITA - UNII:79M2M2UDA9)	MENTHA PIPERITA	3 [hp_X] in 1 mL
PRUNUS SPINOSA FLOWER BUD (UNII: 53Y84VPS2W) (PRUNUS SPINOSA FLOWER BUD - UNII:53Y84VPS2W)	PRUNUS SPINOSA FLOWER BUD	3 [hp_X] in 1 mL
GINGER (UNII: C5529G5JPQ) (GINGER - UNII:C5529G5JPQ)	GINGER	3 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0KOOR)	
XANTHAN GUM (UNII: TTV12P4NEE)	
XYLITOL (UNII: VCQ006KQ1E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73282-0003-1	59 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	08/30/2019	05/31/2025
2	NDC:73282-0003-2	1 in 1 CARTON	04/01/2023	
2		59 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	05/31/2025

