

TUMMY CALM- aloe, carbo vegetabilis, chamomilla, lycopodium clavatum, nux moschata, passiflora incarnata, raphanus sativus, sarsaparilla, zingiber officinale liquid
TJL Enterprises Inc.

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.

Drug Facts:

ACTIVE INGREDIENTS:

Aloe 4X, Carbo Vegetabilis 1X, Chamomilla 3X, Lycopodium Clavatum 3X, Nux Moschata 3X, Passiflora Incarnata 3X, Raphanus Sativus 3X,
Sarsaparilla 3X, Zingiber Officinale 3X

USES:

Temporarily relieves the symptoms of pediatric:

- gas • bloating • upset stomach • hiccups • teething

WARNINGS:

- **Do not use** if outer seal on glass bottle or 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.
- Because product is black, a temporary, 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.

KEEP OUT OF REACH OF CHILDREN:

- **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 outer seal from glass bottle and protective wrap on 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 8 weeks.

INDICATIONS:

Temporarily relieves the symptoms of pediatric:

- gas • bloating • upset stomach • hiccups • teething

INACTIVE INGREDIENTS:

Citric Acid, Glycerin, Potassium Benzoate, Potassium Citrate, Potassium Sorbate, Purified Water, Xylitol

OTHER INFORMATION:

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

PATIENT INFORMATION:

Pure Relief. Naturally.*

Thank you for choosing Tummy Calm homeopathic medicine, the natural alternative for the treatment of gas, upset stomach, and bloating. Tummy Calm is from the makers of Colic Calm, used by more than a million babies...and counting. Our products are recommended by pediatricians, natural health care practitioners, and pharmacists.

Tummy Calm is:

- **Safe, gentle and effective**
- Non-habit forming
- A smart alternative to synthetic chemicals

Frequently Asked Questions

What is the purpose of Tummy Calm and is it safe for my child?

Tummy Calm homeopathic medicine provides relief for discomfort from gas, bloating and upset stomach. Importantly, Tummy Calm is made according to Good Manufacturing Practices (GMP) for over-the-counter homeopathic medicines.

What makes Tummy Calm different from simethicone gas drops?

The active ingredients in Tummy Calm provide multi-symptom relief. According to the principles of homeopathy, each dose gently stimulates the body's ability to heal itself, as opposed to merely suppressing symptoms with synthetic chemicals.

How long will it take to work?

Most children will experience relief with their first dose of Tummy Calm. However, some may take longer before showing noticeable improvement. We recommend giving Tummy Calm up to one week to fully work its wonders.

We encourage you to email us at **customer@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. The dosage can also be mixed with 1 or 2 ounces of water, infant formula or other suitable liquids. Try not to give Tummy Calm immediately

after feeding if baby's stomach is full, as spit up may occur from the added pressure.

Additional tip for toddlers & up: Tummy Calm may also be mixed with water, juice, cereal or other age-appropriate food/drink. Most children enjoy the sweet non-herbal taste, which blends especially well with juice. Dark juices and opaque sippy cups work well if Tummy Calm's dark color is an issue.

If needed, repeat 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 child spits up Tummy Calm?

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

Can my child take other medications while using Tummy 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. If other medications are being used, allow a two-hour window between the other medication and Tummy Calm, so that the effects of the other medication are not lessened.

Does Tummy Calm have any side effects?

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

Tummy 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 Tummy Calm be used for anything other than gas?

Yes. Tummy Calm is helpful in easing pain associated with stomach upset that often accompanies teething. Many toddlers and older children benefit from stomach ache relief with Tummy Calm. Tummy Calm can also provide relief for flatulence and bloating from gas. In addition, a great number of parents swear by Tummy 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 Tummy Calm?

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

Why does my child sleep soundly after taking Tummy Calm?

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

* All active ingredients are derived from natural sources.

** Claims based on traditional homeopathic practice, not accepted medical evidence.

Not FDA evaluated."

Homeopathy and Dilutions

The homeopathic ingredients in Tummy Calm are diluted either to 1X, 3X or 4X 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, and the 4X is obtained by repeating this dilution and succussion process 4 times. Seven of the nine active ingredients in Tummy 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

Tummy 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 Tummy Calm is prepared according to HPUS methods. Charcoal has been used safely in medicinal applications for thousands of years.

The activated charcoal in Tummy 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:

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.

Each dose of Tummy 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

Does Tummy Calm work?

While no product can claim to work for everyone, Tummy Calm does have an impressive track record. Here is what parents are saying:

“We found Tummy Calm to work beautifully within minutes for tummy troubles in my littlest one and my older sons.”

- S. Negash, PhD, Signal Hill, California

“When my children get gas pains and stomach aches, our no-fail, go-to remedy is Tummy Calm.”

- A. Uchio, MD, Los Angeles, California

“Colic Calm has worked wonders for my patients and my own child.

I am thrilled that Tummy Calm is now available, too.”

- G. Lejeune, Pediatrician, Shreveport, Louisiana

“Thanks for another awesome product! We loved Colic Calm when our daughter was a newborn. Now she’s graduated to Tummy Calm. We appreciate the quality and Ashlei still loves the yummy taste.”

- T. Easton, Vero Beach, Florida

We fully stand behind our product, but realize that not every baby will experience relief from Tummy Calm. We encourage you to contact our Tummy Calm Customer Care Team for customized suggestions that can make a difference.

If you do not see noticeable improvement within one week, your baby simply may not have temporary gas discomfort, or the condition may be one that Tummy Calm cannot treat.

Do not use Tummy Calm to treat other medical conditions not indicated on the product packaging. Tummy 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 temporary gassiness 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.

Learn More About Tummy Calm®

Visit **tummycalm.com** or contact us directly:

Email **customercare@tummycalm.com**

Phone **(877) 321-CALM**

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Tummy Calm

IN-006-02

TC-

QUESTIONS:

Distributed by **TJL Enterprises, Inc.**

Long Beach, CA 90803

Call 941-203-4590 visit www.tummycalm.com

PACKAGE LABEL DISPLAY:

Tummy Calm

For symptomatic relief of

Gas, Upset Stomach, & Bloating

- Fast Acting
- Safe & Gentle
- Great Tasting

From the makers of





Colic Calm

Homeopathic Medicine

2 FL. Oz. (59 mL)

24-47 doses

<p>Drug Facts</p> <p>Active Ingredients</p> <p>Aloe 4X, Carbo Vegetabilis 1X, Chamomilla 3X, Lycopodium 3X, Nux Moschata 3X, Passiflora 3X, Raphanus Sativus 3X, Sarsaparilla 3X, Zingiber Officinale 3X</p> <p>Uses</p> <p>Temporarily relieves the symptoms of pediatric: gas • bloating • upset stomach • hiccups • teething</p> <p>Warnings</p> <ul style="list-style-type: none"> • Do not use if outer seal on glass bottle or 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. • Because product is black, a temporary, 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. <p>Questions or Comments? Call 941-203-4590 visit www.tummycalm.com</p>	<h1 style="font-size: 2em;">Tummy Calm®</h1> <p>For symptomatic relief of Gas, Upset Stomach, & Bloating</p> <p>Homeopathic Medicine 2 FL. Oz. (59 mL) 24 - 47 doses</p>	<p>Drug Facts (continued)</p> <p>Directions</p> <p>Weight Dose Under 20 lbs (9 kg) ¼ teaspoon (1.25 mL) Over 20 lbs (9 kg) ½ teaspoon (2.5 mL)</p> <ul style="list-style-type: none"> • Remove outer seal from glass bottle and protective wrap on 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 8 weeks. <p>Other Information</p> <ul style="list-style-type: none"> • Please note: sleep may follow naturally after relief. • Store at room temperature, out of direct sunlight. <p>Inactive Ingredients</p> <p>Citric Acid, Glycerin, Potassium Benzoate, Potassium Citrate, Potassium Sorbate, Purified Water, Xylitol</p> <p>Distributed by T.J.L. Enterprises, Inc. Long Beach, CA 90803</p>
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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13992-006
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACTIVATED CHARCOAL (UNII: 2P3VWU3H10) (ACTIVATED CHARCOAL - UNII:2P3VWU3H10)	ACTIVATED CHARCOAL	1 [hp_X] in 1 mL
CHAMOMILE (UNII: FGL3685T2X) (CHAMOMILE - UNII:FGL3685T2X)	CHAMOMILE	3 [hp_X] in 1 mL
LYCOPODIUM CLAVATUM SPORE (UNII: C88X29Y479) (LYCOPODIUM CLAVATUM SPORE - UNII:C88X29Y479)	LYCOPODIUM CLAVATUM SPORE	3 [hp_X] in 1 mL
NUTMEG (UNII: AEE24M3MQ9) (NUTMEG - UNII:AEE24M3MQ9)	NUTMEG	3 [hp_X] in 1 mL
PASSIFLORA INCARNATA FLOWERING TOP (UNII: CLF5YF5110) (PASSIFLORA INCARNATA FLOWERING TOP - UNII:CLF5YF5110)	PASSIFLORA INCARNATA FLOWERING TOP	3 [hp_X] in 1 mL
RADISH (UNII: EM5RP35463) (RADISH - UNII:EM5RP35463)	RADISH	3 [hp_X] in 1 mL

SMILAX ORNATA ROOT (UNII: 2H1576D5WG) (SARSAPARILLA - UNII:2H1576D5WG)		SMILAX ORNATA ROOT	3 [hp_X] in 1 mL	
GINGER (UNII: C5529G5JPQ) (GINGER - UNII:C5529G5JPQ)		GINGER	3 [hp_X] in 1 mL	
ALOE (UNII: V5VD430YW9) (ALOE - UNII:V5VD430YW9)		ALOE	4 [hp_X] in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
GLYCERIN (UNII: PDC6A3C0OX)				
POTASSIUM BENZOATE (UNII: 763YQN2K7K)				
POTASSIUM CITRATE (UNII: EE90ONI6FF)				
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)				
WATER (UNII: 059QF0KO0R)				
XYLITOL (UNII: VCQ006KQ1E)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13992-006-01	1 in 1 CARTON	08/09/2018	08/12/2025
1		59 mL in 1 BOTTLE, WTH APPLICATOR; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic			08/09/2018	08/12/2025

Labeler - TJL Enterprises Inc. (004042785)

Registrant - Apotheca Company (844330915)

Establishment			
Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(13992-006) , api manufacture(13992-006) , label(13992-006) , pack(13992-006)

Revised: 12/2021

TJL Enterprises Inc.