

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:

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

USES:

- Gas
- Bloating
- Upset stomach
- Hiccups
- Teething

WARNINGS:

- **Do not use** if outer seal imprinted with Tummy Calm logo on bottle or protective wrap on oral dispenser are 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.	1/4 teaspoon (1.25 mL)
Over 20 lbs.	1/2 teaspoon (2.5 mL)

- **Shake well** before use to obtain uniform dark mixture.
- Remove outer seal imprinted with Tummy Calm logo from bottle and protective wrap on oral dispenser.
- When symptoms occur, fill enclosed oral 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, or as directed by physician. Do not exceed 4 full doses in 24 hours.
- Recap bottle and clean oral dispenser.

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:

Thank you for choosing Tummy Calm homeopathic medicine, the natural alternative to simethicone for the treatment of digestive discomfort from gas.

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 & effective
- Non-habit forming or addictive
- 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 customercare@tummycalm.com or call us at (877) 321-CALM 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. For toddlers and up, Tummy Calm naturally settles the stomach, so regurgitation is less likely.

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 child 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-produced, 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 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 the stomach upset that often accompanies teething. Toddlers and older children benefit from stomach ache relief. Tummy Calm also provides relief for hiccups.

How long should each bottle last?

Each bottle contains (47) ¼ teaspoon (1.25 ml) doses for infants under 20 lbs.

or (24) ½ teaspoon (2.5 ml) doses for children over 20 lbs. Some children require more doses than others, depending on the frequency of their symptoms. Discard glass bottle within three months 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.

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

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Homeopathy and Dilutions

The homeopathic ingredients in Tummy 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. Eight 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. The FDA has not evaluated this product.

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. Charcoal has been shown to relieve

symptoms of gas and upset stomach 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, Patel VP, Pitchumoni CS.*

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 child.

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 M E 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 with our money-back guarantee, but realize that not every child 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.

Cease using the product if you do not see noticeable improvement within one week. Your child simply may not have temporary gas discomfort, or the condition may be one that Tummy 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 www.tummycalm.com/refund for full details on our refund policy.

Refunds available to US customers only.

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 child 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 child’s health condition and the use of this or any other medicine.

Pure Relief. Naturally.*

®

Learn More About Tummy Calm®

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

Email **customercare@tummycalm.com**

Phone **(877) 321-CALM**

Win \$2,500 for Your Home Video

Share a home video of Tummy Calm helping your child and if your video is selected you will receive \$2,500. Many will enter, many will win!

For easy-to-follow directions visit:

tummycalm.com/homevideo

TJL-005-* All active ingredients are derived from natural sources.

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1X, 3X or 4X

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.

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

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QUESTIONS:

Distributed by **TJL Enterprises, Inc.**

Long Beach, CA 90803

www.tummycalm.com • (877) 321-CALM

PACKAGE LABEL DISPLAY:

HOMEOPATHIC MEDICINE NDC 13992-006-01

Tummy Calm From the makers of *Colic Calm*

Pure &

Natural

Gas

Relief

FOR
INFANTS
& CHILDREN

Safe & Gentle • Fast Acting • Great Tasting

THE SMART ALTERNATIVE
TO SIMETHICONE

USE ONLY WHEN NEEDED

24-47 Doses Oral Suspension 2 fl. oz. (59 mL)

ACTIVE INGREDIENTS

ALOE 4X, CARBO VEGETABILIS 1X, CHAMOMILLA 3X, LYCOPODIUM 3X, NUX MOSCHATA 3X, PASSIFLORA 3X, RAPHANUS SATIVUS 3X, SARSAPARILLA 3X, ZINGIBER OFFICINALE 3X

DIRECTIONS

- **SHAKE WELL** BEFORE USE TO OBTAIN UNIFORM DARK MIXTURE.
- REMOVE OUTER SEAL IMPRINTED WITH TUMMY CALM LOGO FROM GLASS BOTTLE AND PROTECTIVE WRAP ON ORAL DISPENSER.
- WHEN SYMPTOMS OCCUR, FILL ENCLOSED ORAL DISPENSER UP TO INDICATED DOSE LEVEL AND DISPENSE LIQUID **SLOWLY, DROP-BY-DROP**, INTO MOUTH, BETWEEN CHEEK AND GUMS.
- IF NEEDED, REPEAT ONCE EVERY 60 MINUTES FOR UP TO 3 DOSES, OR AS DIRECTED BY A PHYSICIAN. DO NOT EXCEED 4 FULL DOSES IN 24 HOURS.
- RECAP GLASS BOTTLE AND CLEAN ORAL DISPENSER.

WEIGHT

DOSE

UNDER 20 LBS	1/4 teaspoon (1.25 mL)
OVER 20 LBS	1/2 teaspoon (2.5 mL)

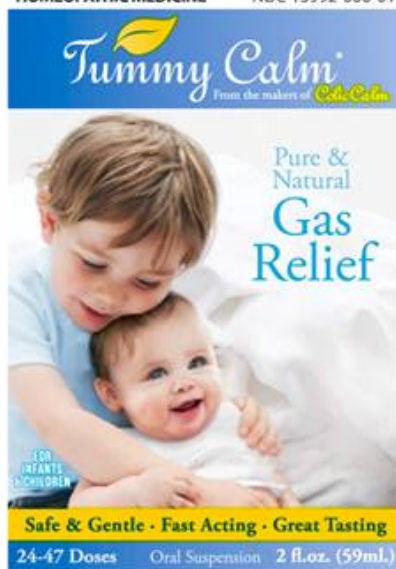
PLEASE NOTE: Sleep may follow naturally after relief.

USES

TEMPORARILY RELIEVES THE SYMPTOMS OF PEDIATRIC GAS, BLOATING, UPSET STOMACH, HICCUPS, & TEETHING.

HOMEOPATHIC MEDICINE

NDC 13992-006-01



WARNINGS

- **DO NOT USE** IF OUTER SEAL IMPRINTED WITH TUMMY CALM LOGO 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.

STORE AT ROOM TEMPERATURE, OUT OF DIRECT SUNLIGHT.

INACTIVE INGREDIENTS

CITRIC ACID, GLYCERIN, POTASSIUM BENZOATE, POTASSIUM CITRATE, POTASSIUM SORBATE, PURIFIED WATER, XYLITOL

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LONG BEACH, CA 90803

TUMMYCALM.COM • (877) 321-CALM • TC-L-006-01

Drug Facts

Active ingredients

Aloe 4X	gas relief, bloating
Carbo Vegetabilis 1X	gas relief, hiccups
Chamomilla 3X	irritability, teething
Lycodium 3X	gas relief, bloating
Nux Moschata 3X	irritability, restlessness
Passiflora 3X	gas relief, upset stomach
Raphanus Sativus 3X	gas relief, upset stomach
Sarsaparilla 3X	gas relief, sour burping
Zingiber Officinale 3X	digestive aid

Purpose

Uses

Temporarily relieves the symptoms of pediatric:
gas • bloating • upset stomach • hiccups • teething

Warnings

- **Do not use** if outer seal imprinted with Tummy Calm logo 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.

Directions

Weight	Dose
Under 20 lbs	1/4 teaspoon (1.25 mL)
Over 20 lbs	1/2 teaspoon (2.5 mL)

- Shake well before use to obtain uniform dark mixture.

(continued)

Drug Facts (continued)

Directions (continued)

- Remove outer seal imprinted with Tummy Calm logo from glass bottle and protective wrap on oral dispenser.
- When symptoms occur, fill enclosed oral dispenser up to indicated dose level and dispense liquid **slowly, drop-by-drop**, into mouth, between cheek and gums, or mix into drink.
- If needed, repeat once every 60 minutes for up to 3 doses, or as directed by a physician. Do not exceed 4 full doses in 24 hours.
- Recap glass bottle and clean oral dispenser.

Other information

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

Inactive ingredients

citric acid, glycerin, potassium benzoate, potassium citrate, potassium sorbate, purified water, xylitol

Questions or comments?

Call (877) 321-CALM

Visit us at

tummycalm.com

Or ask your physician, health care practitioner or pharmacist.

HOMEOPATHIC MEDICINE

NDC 13992-006-01



The
Tummy Calm
Advantage



Naturally Effective

Works Quickly

No Regular Dosing

Also Relieves
Upset Stomach & Hiccups

For Children of All Ages



The product contains medical carbon. It is a homeopathic dilution (see package insert or tummycalm.com for details).

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



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Long Beach, CA 90803

TUMMY CALM

aloe, carbo vegetabilis, chamomilla, lycopodium clavatum, nux moschata, passiflora incarnata, raphanus sativus, sarsaparilla, zingiber officinale liquid

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: CLF5YFS11O) (PASSIFLORA INCARNATA FLOWERING TOP - UNII:CLF5YFS11O)	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	
1		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		08/09/2018	

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: 5/2020

TJL Enterprises Inc.