



THE FACTS ABOUT CBD in Texas

WHAT IS THE COMPASSIONATE USE ACT?

This state law, enacted in 2015, created guidelines for a medical cannabis program. Under the CUA, the state licensed three businesses, including Compassionate Cultivation, to grow cannabis plants and process them into low-THC products rich in non-psychoactive cannabidiol (CBD) specifically for patients with intractable epilepsy.

State-registered physicians can create treatment plans and prescribe CBD medicine to qualifying patients who are permanent Texas residents. Compassionate Cultivation opened the state's first licensed dispensary location in February 2018 and offers delivery services statewide.

HOW DO I QUALIFY TO PRESCRIBE?

The Compassionate Use Registry of Texas (CURT) is the state-regulated platform used by physicians and licensed dispensing organizations to provide low-THC medical cannabis (CBD oil) to patients who hold a valid prescription.

PHYSICIAN REQUIREMENTS

1. Be a state-licensed physician who is board-certified in epilepsy, neurology, or neurophysiology.
2. Register with CURT as a prescribing physician.
3. Enter patient prescriptions in the CURT database, including patient information and their treatment plan.

PATIENT REQUIREMENTS

1. Be a permanent resident of Texas.
2. Have a diagnosis of intractable epilepsy.
3. Hold a valid prescription from a CURT-registered physician.

WHY USE THIS MEDICATION VS. THE OVER-THE-COUNTER CBD PRODUCTS?

EFFICACY: There are wide disparities in CBD and THC content from products sold by unlicensed producers (see charts). This can result in inconsistent treatment.

QUALITY: Licensed CBD oil producers like Compassionate Cultivation are held to extremely rigorous standards for quality, and purity. Products from some unlicensed producers have been shown to include impurities such as bacteria, pesticides and heavy metals.

CONSISTENCY: Compassionate Cultivation adheres to the highest standards in the cannabis industry. The Texas Department of Public Safety tests and inspects CUP licensee facilities weekly.

Compassionate Cultivation	mg/ml		
	CBD	THC	CBD:THC
Lone Star Peppermint (MCT Oil)	103.8	4.5	23:1
Lone Star Cherry (MCT Oil), 2/6/18	100.0	4.5	22:1
Lone Star Unflavored (MCT Oil)	100.8	4.9	22:1
Lone Star Unflavored (Safflower Oil)	103.0	4.9	21:1
Lone Star Cherry (MCT Oil), 3/14/18	103.9	4.9	21:1

Others	CBD	THC	CBD:THC
CW Plus	17.1	0.5	36:1
CW Advanced	65.5	2.0	33:1
Palmetto Harmony	17.0	0.6	28:1
CBD Gold (Compound Pharmacy)	4.4	0.2	22:1
CBD Plus (Compound Pharmacy)	0.32	0.00	N/A
Hemp Extract WAAYB	35.2	1.0	35:1
Haleigh's Hope	21.8	0.7	31:1

Analysis performed using liquid chromatography (LC) on an Agilent 1100 system equipped with a diode array detector (DAD) for UV-Vis spectroscopy.

Early CBD Results Are Strong

Empirical Results from Dr. Karen Keough, as of 1/22/2019*

* Based on 113 patients on treatment between 2 and 10 months.

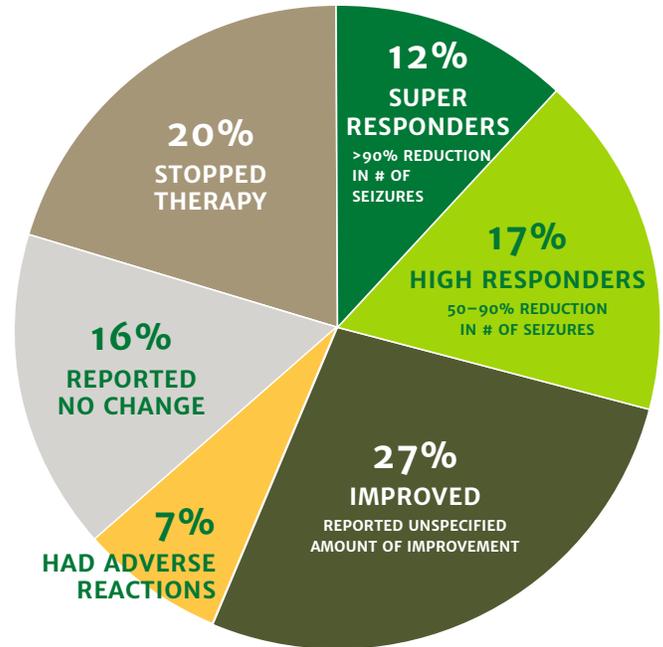
OTHER REPORTED BENEFITS

- » Increased alertness
- » Increased speech
- » Developmental gains
- » Less rescue medication
- » Better sleep
- » Decreased anxiety
- » Decreased behavior issues
- » Marked improvements in cognition

- » Increased appetite
- » Happier demeanor
- » Calming effect
- » Decrease in GI issues

VERY LOW SIDE EFFECTS REPORTED

- » Somnolence
- » Sleepiness
- » Diarrhea
- » GI upset



“CBD has helped Gabriel tremendously,” his mom says. “He is capable of having small conversations now and even able to go get his hair cut. CBD oil was our last resort and it turned out to be the best decision.”

GABRIEL M., 8, lives with intractable epilepsy and autism. After trying every anti-seizure medication on the market with no success, Gabriel began taking our CBD oil in November 2018. He has gone from having 30-plus seizures each day to just five since Nov. 23. His tremors have stopped completely, and he has no side effects from the medication.



“I want to be independent and go to a four-year college.... My hope is that others can benefit from this and that the stigma will eventually be erased by enough advocates like us who go on the record.”

JULIA P., 16, has been taking our CBD oil since February 2018. Not long ago, she had her first-ever clear EEG, a day she called her “best day ever.” Shortly after, she earned her driver’s license. For this teenager, these milestones toward independence are huge.

CBD Dosing Guidelines for Intractable Epilepsy

DR. KAREN KEOUGH

Pediatric Neurologist & Epileptologist; Chief Medical Officer, Compassionate Cultivation

As with any new medication, dosage recommendations for cannabidiol (CBD) medicines are best established according to scientific research and high-quality anecdotal evidence from individual patients. CBD does not come with a dosing range approved by the FDA. New FDA-approved drugs include dose ranges approved in clinical trials; the actual dosing ranges become apparent as more patients use the medicine and as both prescribers and patients determine the dosing that works.

GENERAL GUIDELINES FOR CBD DOSING

Because the Texas program is new, there is a limited knowledge base at this time; it will grow as more patients join the program and prescribers learn

what is working and how patients respond to CBD treatment.

I devised these guidelines based on published data from clinical trials, and have refined the approach based on experience with more than 100 patients I have written prescriptions for since February 2018. This is a starting point, with the expectation that some patients may require higher doses. For each patient, CBD dosing will depend on:

- » Product formulation (e.g. CBD concentration, THC concentration). Compassionate Cultivation's Lone Star Tincture is 100 mg/ml CBD with 5 mg/ml THC (0.5%).
- » Patient characteristics, including weight, age and medications patient is already taking. One common seizure medication often used in refractory patients – clobazam (Onfi) – has a strong interaction with CBD. Patients taking Onfi should start on lower



CBD doses and be titrated more gradually even if Onfi is the only other seizure medication the patient is taking when initiating CBD treatment.

- » Initial dose and rate of titration both need to be considered.
- » Medically sensitive patients, such as children under two or those taking multiple concomitant seizure medications, should be started at a lower dose and titrated more slowly. Less sensitive patients can be started at a somewhat higher initial dosage.

Dose increments of <0.1ml are not feasible to measure, so round to 0.1 ml instead of 0.05 ml increments. The half-life is long, so once/day dosing is fine for small doses; split to twice/day if volume makes oral absorption difficult or if the dose starts to cause sleepiness.

Doses should be given in cheek or under tongue ideally; if swallowed, should be given with some fatty food to increase absorption.

Higher doses have been utilized in some clinical trials, but may not be necessary in all patients to achieve good seizure control. These higher doses may be well tolerated, but we need more experience with the Lone Star product to understand the ranges our patients need for optimal response with minimal side effects.

LOW DOSE INITIATION IN CHILDREN

- » 0.5 mg/kg/day, minimum dose 10 mg = 0.1 ml.
- » Increase every 1-2 weeks by 0.5-1 mg/kg/day, rounding to nearest 10 mg (0.1 ml increments) as long as side effects don't interfere.
- » Target dose 2-10 mg/kg/day; average is 2-6 mg/kg/day.

LOW DOSE IN ADULTS (OR CHILDREN WEIGHING >50 KG)

- » 25 mg twice daily.
- » Increase every 1-2 weeks by 25 mg/dose.
- » Target dose 100-300 mg twice daily if tolerated. Stop sooner if seizures stop or side effects prevent further dose increases.

HIGHER DOSE INITIATION IN CHILDREN

- » 1 mg/kg/day, minimum 10 mg = 0.1 ml.
- » Increase every 1-2 weeks by 1 mg/kg/day, as long as side effects do not interfere.
- » If side effects are a problem, go up more gradually with more time between dose increases.
- » Target dose 2-10 mg/kg/day, average is 2-6 mg/kg/day.

HIGHER DOSE IN ADULTS (OR CHILDREN WEIGHING >50 KG)

- » 50 mg twice daily.
- » Increase every 1-2 weeks by 50 mg/dose.
- » Target dose 100-300 mg twice daily if tolerated. Stop sooner if seizures stop or side effects prevent further dose increases.

For the complete Dosing Guidelines document, as well as full references for research and clinical trials on CBD treatment, visit texasoriginalcc.com/physicians.

Compassionate Cultivation's Product Family Is Growing

LONE STAR TINCTURE is a panel of condition-specific cannabidiol (CBD) tinctures that are specifically formulated and lab-tested to treat qualifying patients with intractable epilepsy under the Texas Compassionate Use Act.

Formulated with high CBD levels, low levels of psychoactive tetrahydrocannabinol (THC) and minimal inactive ingredient additives, the Lone Star line is produced using hydrocarbon-free, high purity CO₂ extraction processes and rigorous state-of-the-art testing to ensure consistent medicine that is free of heavy metals, microbes and chemical contaminants.

As part of Compassionate Cultivation's commitment to transparency, test results are publicly available at <https://texasoriginalcc.com/physicians>.

ACTIVE INGREDIENTS (Single Concentration)

100 mg CBD per 1 mL of tincture
5 mg THC per 1 mL of tincture

INGREDIENTS

CO₂ extracted cannabis oil
USP-grade coconut MCT oil*
Food-grade essential oil flavoring

FLAVORS

Cherry, Mint, Unflavored

PACKAGING

Tamper-evident, child-resistant, clear glass bottle labeled with traceability and dosing information. Comes with 1 mL medical-grade syringe.



*Safflower oil is available for patients with an aversion to MCT oil.
All safflower oil products are unflavored.

Available sizes*	CBD	THC	Price
7.5 mL	750 mg	37.5 mg	\$94.50
15 mL	1500 mg	75 mg	\$180
30 mL	3000 mg	150 mg	\$342

*Mouth spray currently available in 15 mL size only.

The retail cost for a single mg of CBD is approximately 13¢. We offer a 10% discount for in-dispensary pickup (cannot be combined with other discounts). Military families receive a 10% discount with valid proof of service (active or retired).



LONE STAR MOUTH SPRAY

is our newest product. Lone Star Spray comes in the same concentration as our tincture but in a new, spill-proof container with much simpler administration. This new formulation, another first in the state of Texas, has some compelling benefits for patients and their caregivers, including: enhanced absorption and ease of delivery; consistent dose delivery – especially for substitute caregivers – and a light, portable, easy-to-use package. The pump / spray action produces small droplets of medicine that coat the inside of the mouth resulting in an increased absorption rate. As a result, Lone Star Spray may also be a better option for patients with G-tubes.

ACTIVE INGREDIENTS

The final CBD/THC concentrations are the same as Lone Star Tincture (10% CBD/0.5% THC). A single spray dispenses roughly 10mg (0.1mL) of the suspension, which equates to roughly 10mg CBD per spray.

INGREDIENTS

Lone Star Mouth Spray is formulated similarly to our tincture, using CO₂-extracted cannabis oil,

USP-grade MCT oil or safflower oil, and natural flavoring oils and extracts. This product has been formulated using food-grade, 190-proof, organic ethanol (24% by weight) to make its viscosity suitable for spraying.

FLAVOR

Mint

PACKAGING

Child-resistant plastic bottle with same labeled box as tincture.