



## Medical Cannabis and Cannabidiol (CBD) Frequently Asked Questions

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### What is medical cannabis?

The term medical cannabis is used to describe cannabis that is recommended by a doctor or other licensed prescribing health care provider (e.g. nurse practitioner or physician assistant) for the treatment of a medical condition. There is no meaningful difference between medical cannabis and cannabis sold through other regulated means such as in recreational dispensaries. Medical cannabis is generally used to refer to a large variety of cannabis products including dry leaf products and tinctures of isolated cannabinoids such as cannabidiol (CBD). Because medical cannabis can be used in the treatment of a medical condition, it is critical to treat it as any other medication and consult your health care provider who can best monitor your health and any medication interactions medical cannabis may have.

### What is cannabidiol (CBD)?

Cannabidiol (CBD) is a compound derived from the Cannabis Sativa L. plant. CBD is one of over 100 chemicals, also known as cannabinoids, found in the cannabis plant. Unlike tetrahydrocannabinol (THC), another cannabinoid found in the plant, CBD does *not* cause intoxication or euphoria (often referred to as the “high”). While derived from the cannabis plant, CBD does not produce the same effect as the whole plant.

### What is the Epilepsy Foundation’s position on medical cannabis and CBD?

The Epilepsy Foundation is committed to supporting provider-directed care and to exploring and advocating for all potential treatment options, including medical cannabis and CBD. We support lifting federal barriers to research on cannabis and CBD and support access to these potential therapies, through state-regulated programs, for individuals when other treatment options have failed them. If an individual and their health care team feel that the potential benefits of medical cannabis for uncontrolled epilepsy outweigh the risks, then the individual should have safe, legal access to medical cannabis.

Medical cannabis and/or CBD must be used under the close supervision of your treating physician or prescribing provider. The combination and amount of medications an individual takes to control their seizures is specifically formulated for them depending on a number of factors. While there may be some trial-and-error in finding the right combination of medications that work for you, once a treatment regimen is determined it is critical to continue that regimen as instructed. If an individual unilaterally, without the consultation or supervision of their treating physician, introduces medical cannabis and/or CBD to their treatment plan, they could be at a greater risk of breakthrough seizures, side effects, or other complications.

### What is the legal status of CBD?

On December 12, 2018, Congress passed, and the President later signed into law, the 2018 Farm Bill which included provisions legalizing the cultivation of hemp and hemp-based products, including CBD derived from hemp. Previously, CBD was considered cannabis under the federal definition of the term. As such, cannabis, and by extension CBD, were considered Schedule I substances, which means there was no acceptable medical use and the substance had a high potential for abuse. Under the 2018 Farm Bill, the federal definition of hemp was changed to encompass any cannabis plant or product derived from a cannabis plant that contains less than 0.3% THC by dry weight. The Farm Bill further amended the Controlled Substances Act to exempt hemp from the definition of cannabis, meaning hemp and its derivatives are no longer Schedule I substances. This change, however, does not mean that all hemp-derived products, including CBD, are medically appropriate for all individuals living with epilepsy.

### What is the legal status of medical cannabis?

To date, 46 states and the District of Columbia have passed legislation allowing for the medical use of cannabis and/or



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CBD. The 2018 Farm Bill does not change existing laws surrounding state medical cannabis programs. Further, there is no federal standard for medical cannabis programs so the requirements vary from state-to-state. It is imperative that you understand the laws and regulations surrounding cannabis use in your state, and that you follow those laws and regulations. You are only protected from state prosecution if you comply with the requirements set out in your individual state's medical cannabis laws.

While medical cannabis and/or CBD is legal per state law in a majority of states and the District of Columbia, cannabis and cannabis-derivatives remain Schedule I, and thus illegal, under federal law. Under federal law, cannabis is defined as any Cannabis Sativa L. plant or product with more than 0.3% THC by dry weight. Individuals should be aware that shipping or traveling across state lines with cannabis or any cannabis product is against federal law and can lead to federal prosecution.

### **Are there any side effects or drug interactions associated with medical cannabis or CBD?**

Medical cannabis and CBD are not without side effects and may affect the efficacy of other medications you take. In controlled research trails of a plant-based formulation of CBD (Epidiolex<sup>®</sup>), the most common side effects were sleepiness, sedation and lethargy, elevated liver enzymes, decreased appetite, diarrhea, rash, fatigue, malaise and weakness, and insomnia. There is also the risk of liver injury, generally mild, but which raises the possibility of rare, but more severe injury. This was seen more often when CBD was combined with valproic acid (Valproate, Depakote<sup>™</sup>).

CBD can significantly interact with a number of other medications taken for seizures. CBD can slow the ability of the liver to eliminate a breakdown product of clobazam. This can cause additional sleepiness and may mean a reduction in clobazam doses is needed. There may also be interactions with topiramate (Topamax<sup>™</sup>, Qudexy<sup>™</sup>, Trokendi<sup>™</sup>), rufinamide (Banzel<sup>™</sup>), eslicarbazepine (Aptiom<sup>™</sup>) and zonisamide (Zonegran<sup>™</sup>).<sup>1</sup> In addition, the studies using Epidiolex<sup>®</sup> show that CBD can interact with medications other than those taken for epilepsy, so it is important to discuss CBD use with any other physician or provider who prescribes medication.

### **Will medical cannabis or CBD replace my other medications?**

While there have been some instances in which individuals were able to wean off certain medications under medical supervision while taking CBD, it is not true for every individual and you should not make those decisions without the guidance and supervision of your treating physician or prescribing provider. Anticonvulsant medications, including Epidiolex<sup>®</sup> and CBD, are not one-size-fits-all. What may work for one person may not work for another. Only your treating physician or prescribing provider is in the position to judge whether a particular medication or treatment may work for you and whether it is safe or advisable to begin weaning off medications under close medical supervision.

### **What do I do if my physician or prescribing provider will not recommend medical cannabis or CBD?**

As with other treatment options, controlling your seizures may involve trial and error. A particular treatment that works for one person may not be beneficial for everyone. When making decisions about changing your treatment regimen, your physician or prescribing provider considers a number of factors including overall health status, current medications, seizure control, and medical history. He or she is in the best position to determine whether the potential benefits of medical cannabis or CBD outweigh possible risks based on your individual situation. If your physician does not believe you will benefit from medical cannabis or CBD, you should not unilaterally change your treatment plan – especially without first telling your physician or prescribing provider.

As with all your medical care, you need to develop a relationship of trust with your physician or prescribing provider. If

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<sup>1</sup> How Does Cannabidiol Interact With Antiepileptic Drugs?, *Neurology Reviews*. 2017 January;25(1):11.



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you feel this relationship does not or cannot exist, there is always the option of seeking alternate care. In either case, use of this treatment, as with all seizure medications, should be under a doctor's supervision.

### **Is there any difference in the commercial-grade CBD I purchase online or from a health food store and the dispensary-grade CBD sold in medical dispensaries?**

Not all CBD products are the same. Many products claiming to have CBD also have other chemicals, bacteria, or mold. Further, there is no consistency within these products, which may cause seizures and/or side effects to change from month to month. This is another reason why individuals should not use CBD without consulting and informing their treating physician.

Dispensary-grade CBD products and medical cannabis sold in state-run medical cannabis facilities must comply with state safety and testing guidelines laid out in state law and regulations. However, 1 in 5 failed in California when tested. Many state cannabis laws provide safety mechanisms from growth of the plant to the final product in an attempt to ensure that the final, ingestible product does not contain any foreign compounds or prohibited chemicals. Further, state laws and regulations have labeling requirements for medical cannabis and products which are required to be truthful, supported by testing, and contain information consumers should know including CBD levels and presence and amount of other ingredients.

Over-the-counter commercial-grade CBD products that are not sold in state-run medical cannabis facilities are not required to comply with the same laws and regulations that are in place for products sold at a medical cannabis dispensary. Currently, there are no federal standards, and few state standards, for the cultivation or manufacturing of commercial-grade CBD products. Consumers should be aware that the FDA does monitor some commercial-grade CBD products to ensure they are not making unsubstantiated medical claims, and to make sure product labels are truthful and contain the cannabinoids and other compounds or chemicals they claim. Because of the lack of robust oversight in the commercial-grade CBD space, the FDA has found that some products were making unsubstantiated medical claims or did not contain the amount of CBD they claimed to contain, including, at times, containing no CBD at all.<sup>2</sup>

### **Are there currently any FDA-approved therapies derived from CBD?**

On June 25, 2018, the FDA approved a CBD product, Epidiolex<sup>®</sup>, a purified (>98% CBD) plant-based formulation that is oil-based, for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in individuals two years of age or older. This is the first FDA-approved plant-based cannabis derived medication, and it is the first FDA-approved treatment option for individuals with Dravet syndrome.

Three controlled clinical trials of Epidiolex<sup>®</sup> were conducted in 516 patients with Dravet Syndrome or Lennox Gastaut Syndrome. The results<sup>3</sup> showed that Epidiolex<sup>®</sup> was effective in reducing the frequency of seizures when compared with placebo. In each of the three trials, either Epidiolex<sup>®</sup> or placebo was added to the patients' existing medication regimen.

For more information on FDA-approved CBD like Epidiolex<sup>®</sup>, visit [advocacy.epilepsy.com/statefdapathway](https://advocacy.epilepsy.com/statefdapathway).

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<sup>2</sup> Office of the Commissioner. "Public Health Focus - Warning Letters and Test Results for Cannabidiol-Related Products." *U S Food and Drug Administration Home Page*, Center for Drug Evaluation and Research, [www.fda.gov/newsevents/publichealthfocus/ucm484109.htm](https://www.fda.gov/newsevents/publichealthfocus/ucm484109.htm).

<sup>3</sup> Devinsky, O., Cross, J. H., Laux, L., Marsh, E., Miller, I., Nabbout, R., . . . Wright, S. (2017). Trial of Cannabidiol for Drug-Resistant Seizures in the Dravet Syndrome. *New England Journal of Medicine*, 376 (21), 2011-2020. doi:10.1056/nejmoa1611618, <https://www.nejm.org/doi/full/10.1056/NEJMoa1611618>; Devinsky, O., Patel, A. D., Cross, J. H., Villanueva, V., Wirrell, E. C., Privitera, M., . . . Zuberi, S. M. (2018). Effect of Cannabidiol on Drop Seizures in the Lennox-Gastaut Syndrome. *New England Journal of Medicine*, 378(20), 1888-1897. doi:10.1056/nejmoa1714631, <https://www.nejm.org/doi/full/10.1056/NEJMoa1714631>.



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### **How is Epidiolex<sup>®</sup> different from commercial grade CBD sold over-the-counter and in dispensaries?**

Similar to other medications approved by the FDA, Epidiolex<sup>®</sup> has been subject to controlled clinical trials to test the safety and efficacy of the medication, along with careful review through the FDA's drug approval process. Other CBD products purchased over-the-counter or through a dispensary may not have received the same level of quality control and review as medical-grade products approved by the FDA.

Epidiolex<sup>®</sup> is a pharmaceutical-grade version of CBD oil and is assured to have uniform strength and consistent delivery. This uniformity provides reliability and stability of each dose of Epidiolex<sup>®</sup> that commercial-grade CBD may lack.

**For additional information and the latest on medical cannabis and CBD laws,  
visit [advocacy.epilepsy.com/medical-cannabis](https://advocacy.epilepsy.com/medical-cannabis)**