



Cannabinoids 101: Understanding CBD

 Epidiolex[®]
(cannabidiol)

Please see full Important Safety Information at the end of this brochure and click [here](#) for full Prescribing Information.

CBD: Know the facts

You may have heard about cannabinoids and how they have been suggested as a possible treatment for many different conditions. But with all the information out there, it can be hard to know what to believe and how to understand the difference between what's been studied in clinical trials and what hasn't. This brochure will help you understand the facts so you're as informed as possible.



Where it all begins

Cannabis, also known by its scientific name *Cannabis sativa* L., is a plant that's been used for thousands of years as fiber, food, oil, and for its potential therapeutic effects.



The cannabis plant is the source of many different products



Marijuana is a dried mixture of leaves and flowers from the cannabis plant.



Medical marijuana is cannabis used to treat disease or ease symptoms; however, there is no scientifically accepted definition. It is difficult to study the possible medical benefits of cannabis because each plant and each variety contains many types of compounds in various amounts.



Hemp is cannabis that's bred for the fiber in its stalks, which is used for clothing and textiles, and/or the oil from its seeds, which is used nutritionally.



Hemp oil or hemp seed oil comes from compressed cannabis seeds that contain little or no cannabinoids.



FDA-approved medications are developed and studied to meet all Food and Drug Administration (FDA) standards for quality, safety, and effectiveness.

What's the difference?

While each of the products listed above are either cannabis or derived from the cannabis plant, they are all different. Inside each cannabis plant are compounds called phytocannabinoids—a single plant can contain over 100 different kinds. You may have heard of the cannabinoids CBD (cannabidiol) and THC (Δ^9 -tetrahydrocannabinol), as they are the most common cannabinoids and the most studied.

CBD vs THC

Although CBD and THC have similar chemical structures, they have different shapes and behave differently inside the body. This is why THC creates a euphoric effect, or “high,” and CBD does not.

Now that you know the basics about cannabinoids, get to know the first and only FDA-approved prescription CBD:

EPIDIOLEX is the first and only FDA-approved prescription CBD for treatment of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex in patients 1 year of age and older.

Contains a highly purified form of cannabidiol (CBD) that comes from the cannabis plant. The active ingredient is nearly 100% CBD.

EPIDIOLEX is believed to work differently from other prescription seizure medicines, but the exact mechanisms of action (how it works) are unknown.

Every bottle of EPIDIOLEX has the exact ingredients listed on the package, ensuring consistent concentrations of CBD with every batch and delivering quality that meets FDA standards.

Do not take EPIDIOLEX if you are allergic to cannabidiol or any of the ingredients in EPIDIOLEX.

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Confidence in each bottle

Here's why you can trust what goes into each bottle of EPIDIOLEX.



Naturally grown

The active ingredient in EPIDIOLEX is not synthetic. It is a highly purified form of CBD medicine that is greenhouse-grown from non-GMO plants.

EPIDIOLEX is contaminant free. Strict regulations make sure EPIDIOLEX contains no toxic heavy metals, no pesticides, and no contaminants.



Manufactured to meet the high standards of the FDA

EPIDIOLEX is made according to the World Health Organization's Good Agriculture Practices, the FDA's current Good Manufacturing Practices, and other strict regulations.

For dispensary, online, or hemp products, there are no federal standards (eg, quality, consistency, CBD concentration), and regulations vary by state.

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The FDA difference

EPIDIOLEX is the only FDA-approved CBD product and has been clinically studied in a comprehensive, controlled trial program.

You can only get FDA-approved medicines like EPIDIOLEX through a doctor's prescription and at the pharmacy—not a dispensary or online.

In fact, studies conducted by the FDA and other researchers found that several dispensary and online CBD products did not have the levels of CBD they claimed.*†‡ However, every bottle of EPIDIOLEX has the exact ingredients listed on the package, ensuring consistent concentrations of CBD with every batch and delivery of quality that meets FDA standards.



*Source: <https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products>

†Source: Vandrey R, Raber JC, Raber ME, Douglass B, Miller C, Bonn-Miller MO. Cannabinoid dose and label accuracy in edible medical cannabis products. *JAMA*. 2015;313(24):2491-2493.

‡Source: <https://www.frontiersin.org/journals/pharmacology/articles/10.3389/fphar.2024.1335441/full>

Consistent from batch to batch

Every bottle of EPIDIOLEX contains the exact ingredients listed on the package, per FDA regulation.

- All of this ensures that we're not only meeting or exceeding quality specifications for an active ingredient, but we're also guaranteeing the batch-to-batch consistency of our product

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Understanding the differences between products in the market

There are many products that claim to have a medical benefit, but they're not all created equal. FDA-approved products undergo a strict level of regulation and testing to evaluate their safety and efficacy.

MOST STUDIED AND REGULATED

FDA-approved medicines

A designation from the FDA is only given after thorough controlled clinical studies are conducted to evaluate the safety and efficacy profiles of new compounds. All information about contents, shelf stability, and batch consistency must be provided, and the FDA conducts regular inspections to confirm that a company's processes continue to meet their standards.

Dietary supplements

Regulated separately from conventional food and medicines, these are products that add nutritional value with either a vitamin, mineral, amino acid, concentrate, metabolite, herb or other botanical, or substance to increase total dietary intake. The FDA has said that CBD may not be sold as a dietary supplement.

“Nutraceuticals”

This is a commonly used word with no uniformly accepted definition and no FDA-recognized category. Individual nutraceuticals are not tested for medical or health benefits.

The FDA has said that selling CBD as a nutraceutical would be against FDA regulations.

LEAST STUDIED AND REGULATED



Get the conversation started

Now that you know the facts about CBD and how EPIDIOLEX is produced, you probably have some questions for your doctor.

1. How is CBD different from THC?
2. Is a cannabis-based medicine such as EPIDIOLEX right for me?
3. Why might I choose an FDA-approved CBD?
4. How is EPIDIOLEX different from a dispensary, online, or in-store product?
5. Can EPIDIOLEX be added to my current medicines?
6. Are there any important considerations regarding safety or interactions with other medicines?
7. Can EPIDIOLEX be taken with my current dietary therapy, eg, the ketogenic diet?

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Important Safety Information & Indications

What is the Most Important Information I Should Know About EPIDIOLEX (cannabidiol)?

Do not take if you are allergic to cannabidiol or any of the ingredients in EPIDIOLEX.

EPIDIOLEX may cause liver problems. Your doctor may order blood tests to check your liver before and during EPIDIOLEX treatment. In some cases, EPIDIOLEX treatment may need to be stopped. Call your doctor right away if you start to have any of these signs and symptoms of liver problems during treatment with EPIDIOLEX:

- loss of appetite, nausea, vomiting
- fever, feeling unwell, unusual tiredness
- yellowing of the skin or the whites of the eyes (jaundice)
- itching
- unusual darkening of the urine
- right upper stomach area pain or discomfort

EPIDIOLEX may cause you to feel sleepy, which may get better over time. Other medicines (e.g., clobazam) or alcohol may increase sleepiness. Do not drive, operate heavy machinery, or do other dangerous activities until you know how EPIDIOLEX affects you.

Like other antiseizure medicines, EPIDIOLEX may cause suicidal thoughts or actions in a very small number of people, about 1 in 500. Call your doctor right away if you have any signs of depression or anxiety, thoughts about suicide or self-harm, feelings of agitation or restlessness, aggression, irritability, or other unusual changes in behavior or mood, especially if they are new, worse, or worry you.

Take EPIDIOLEX exactly as your doctor tells you. Do not stop taking EPIDIOLEX without first talking to your doctor. Stopping an antiseizure medicine suddenly can cause serious problems.

Please see continued Important Safety Information on the following page and click here for full [Prescribing Information](#).

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Important Safety Information & Indications (cont'd)

What Else Should I Know When Taking EPIDIOLEX?

The most common side effects of EPIDIOLEX include increase in liver enzymes, sleepiness, decreased appetite, diarrhea, fever, vomiting, feeling very tired and weak, rash, sleep problems, and infections.

EPIDIOLEX may affect the way other medicines work, and other medicines may affect how EPIDIOLEX works. Do not start or stop other medicines without talking to your doctor. Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, herbal supplements, and cannabis-based products.

What Additional Information Applies to Women?

If you are pregnant or plan to become pregnant, EPIDIOLEX may harm your unborn baby, and medicines like EPIDIOLEX may be passed into breast milk. You and your doctor will decide if you should take EPIDIOLEX and about the best way to feed your baby while taking EPIDIOLEX. If you become pregnant while taking EPIDIOLEX, discuss registering with the EPIDIOLEX Pregnancy Surveillance Program (855-272-7158 or [epidiolexpregnancystudy.com](https://www.epidiolexpregnancystudy.com)) and the North American Antiepileptic Drug Pregnancy Registry (888-233-2334 or [aedpregnancyregistry.org](https://www.aedpregnancyregistry.org)). The purpose of these registries is to collect information about the safety of antiseizure medicines during pregnancy.

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Important Safety Information & Indications (cont'd)

What is EPIDIOLEX (cannabidiol)?

EPIDIOLEX is a prescription medicine that is used to treat seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex in patients 1 year of age and older. It is not known if EPIDIOLEX is safe and effective in children under 1 year of age.

Please read the EPIDIOLEX [Medication Guide](#) and [Instructions for Use](#) for additional important information.

You are encouraged to report side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088. You may also contact Jazz Pharmaceuticals at 1-800-520-5568.

Please click here for full [Prescribing Information](#).

To learn more, visit
EPIDIOLEX.com/fda-approved-cbd



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