



# Cannabinoids 101: Understanding CBD

 Epidiolex<sup>®</sup>  
(cannabidiol)

Please see Important Safety Information at the end of this brochure.  
Please refer to the Prescribing Information, including the Medication Guide  
and Instructions for Use, on [EPIDIOLEX.com](https://www.epidiolex.com)

# 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 ( $\Delta^9$ -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 CBD:



EPIDIOLEX is the first and only FDA-approved prescription CBD for treatment of seizures associated with Dravet and Lennox-Gastaut syndrome (LGS) in patients 2 years of age and older, and the first FDA-approved treatment for Dravet.

EPIDIOLEX contains a highly purified form of CBD extracted directly from plants; the active ingredient is nearly 100% CBD.

EPIDIOLEX is believed to target multiple treatment pathways and is different from other prescription seizure medicines. The exact mechanisms of action of EPIDIOLEX (how it works) are unknown.

EPIDIOLEX is rigorously tested to ensure quality and consistency in every bottle.

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.



### FDA-approved for your peace of mind

EPIDIOLEX went through the rigorous FDA-approval process to ensure it is consistent and stable, with a safety and efficacy profile that has been thoroughly evaluated. FDA-approved medicines are not available in dispensaries. In fact, the FDA has evaluated some of these products and noted that they did not contain the levels of CBD they claimed.\*



### The natural approach

EPIDIOLEX is extracted directly from plants specifically grown to yield a high amount of CBD. EPIDIOLEX is not synthetic (not made in a lab).



### Attention to detail: from the ground up

Each cannabis plant we use is grown in its own container with controlled light, water, and soil, in our highly regulated, state-of-the-art greenhouses, ensuring:

- ⊗ No contaminants
- ⊗ No pesticides
- ⊗ Not genetically modified
- ⊗ No fungicides
- ⊗ No heavy metals

\*Source: <https://www.fda.gov/NewsEvents/PublicHealthFocus>.



## Manufactured to meet the high standards of the FDA

We meet high standards for quality in line with the World Health Organization's Good Agriculture Practices and the FDA's Current Good Manufacturing Practices. During manufacturing, any potential bacteria are killed, and THC and any other residual components are minimized to produce a highly purified form of CBD.

## 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.

### 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 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 you start taking EPIDIOLEX and during 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 antiepileptic drugs, EPIDIOLEX may cause suicidal thoughts or actions in a very small number of people, about 1 in 500. Call a healthcare provider 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 healthcare provider tells you. Do not stop taking EPIDIOLEX without first talking to your healthcare provider. Stopping a seizure medicine suddenly can cause serious problems.

#### What Else Should I Know When Taking EPIDIOLEX?

The most common side effects of EPIDIOLEX include sleepiness, decreased appetite, diarrhea, increase in liver enzymes, 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 healthcare provider. Tell healthcare providers about all the medicines you take, including prescription and over-the-counter medicines, vitamins, herbal supplements, and cannabis-based products.



## **Important Safety Information & Indications (continued)**

### **What Additional Information Applies to Women?**

If you are pregnant or plan to become pregnant, EPIDIOLEX may harm your unborn baby. You and your healthcare provider will have to decide if you should take EPIDIOLEX while you are pregnant.

If you become pregnant while taking EPIDIOLEX, talk to your healthcare provider about registering with the North American Antiepileptic Drug Pregnancy Registry (by calling 1-888-233-2334). The purpose of this registry is to collect information about the safety of antiepileptic medicines during pregnancy.

Because many medicines like EPIDIOLEX are passed into breast milk, talk to your healthcare provider about the best way to feed your baby while taking EPIDIOLEX.

### **What is EPIDIOLEX (cannabidiol)?**

EPIDIOLEX is a prescription medicine that is used to treat seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older.

It is not known if EPIDIOLEX is safe and effective in children under 2 years of age.

**Please refer to 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](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.**

**You may also contact Greenwich Biosciences at 1-833-424-6724 (1-833-GBIOSCI).**



For the latest updates, information, and stories about EPIDIOLEX, like and follow us on **Facebook @EPIDIOLEX**, and subscribe to our **YouTube channel**.