

Epidiolex (Cannabidiol) Primer: Frequently Asked Questions for Patients and Caregivers

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On June 25, 2018, the first plant-derived, purified pharmaceutical-grade cannabidiol (CBD) medication, Epidiolex (Greenwich Biosciences Inc, Carlsbad, CA), was approved in the United States by the US Food and Drug Administration (FDA). Epidiolex is for patients 2 years and older with Dravet syndrome (DS) or Lennox-Gastaut syndrome (LGS), and has revolutionized the treatment of medically refractory seizures in these patients.^{1–4} The road to widespread therapeutic use of CBD and its recent approval for seizure disorders has been a long one.^{1–4}

Four pivotal randomized, double-blind, multicenter clinical trials evaluated the use of CBD in patients with DS and LGS with regard to the efficacy and

safety in convulsive and drop seizure, respectively (GWPCARE 1–4).⁴ All trials demonstrated a significant absolute reduction in seizure frequency.^{1–4} The most common adverse drug effects ($\geq 10\%$) depicted in the trials included somnolence, fatigue, rash, decreased appetite, diarrhea, insomnia, infection, and elevated transaminases.^{1–4}

Epidiolex is a CBD-only component, with no Δ^9 tetrahydrocannabinol [Δ^9 THC].¹ THC is the psychoactive component of cannabis, responsible for appetite stimulation and a euphoria sensation.^{5,6} When referring to cannabis it is a collective term for 3 species of hemp plants, including *Cannabis sativa*, *Cannabis indica*, and *Cannabis ruderalis*.^{5,6} Both THC and CBD are

Table. Epidiolex (Cannabidiol): Frequently Asked Questions for Patients and Caregivers

Question	Response
What is Epidiolex?	It is an FDA-approved, plant-derived, purified prescription cannabidiol, indicated for the treatment of seizures in patients 2 years and older. ⁹
Is a state permit required for Epidiolex?	No, it is an FDA-approved prescription medication (Schedule V), making it legal under federal law; therefore, no state permit is necessary.
Are cannabidiol and marijuana the same thing?	No, CBD is derived from the cannabis (marijuana) plant; however, it is entirely different from marijuana and has none of the euphoric properties or abuse potential. CBD and THC are the 2 most frequent chemicals found in the plant.
Does Epidiolex contain THC?	No. However, other CBD, “hemp,” and medical marijuana products available may contain small amounts of THC. These products are not regulated; therefore, there is variability in how much THC has been removed from these products and how much CBD is in these products.
Are Epidiolex and CBD the same thing?	Epidiolex is the brand name for the pharmaceutical-grade cannabidiol oil product produced by Greenwich, whereas other CBD, “hemp,” and medical marijuana products available may contain small amounts of THC. These products are not regulated; hence, there is variability in how much THC has been removed from these products and how much CBD is in these products.
Is it possible to test positive for marijuana while on this drug?	While on Epidiolex, patients may test positive on urine drug screenings. Patients/parents should inform the drug testing site that they are taking Epidiolex as prescribed by their doctor.
Will Epidiolex cause my child to have euphoria-like experiences (i.e., the “high”)?	No, Epidiolex will not create euphoric effects because it does not contain any THC, which is the chemical compound in marijuana that creates the “high” effect.
Can my child become addicted to Epidiolex?	No
How is Epidiolex formulated?	Epidiolex comes in a strawberry-flavored, sesame oil–based oral solution.

CBD, cannabidiol; FDA, US Food and Drug Administration; THC, tetrahydrocannabinol

Table. Epidiolex (Cannabidiol): Frequently Asked Questions for Patients and Caregivers (cont.)

Question	Response
If my child is allergic to strawberries or sesame seeds, can they take Epidiolex?	Epidiolex can be given to patients with strawberry allergies because it only contains strawberry flavoring. However, as with any allergy, it is important to discuss with your child's physician first. Epidiolex is not recommended for patients who have a sesame seed allergy because Epidiolex is made in sesame oil.
How should Epidiolex be stored?	It should be stored at room temperature and can be used within 12 weeks of opening. It is important to throw away any remaining medication after 12 weeks.
Does Epidiolex interact with my child's other medications?	There is a possibility that Epidiolex may interact with other prescription, non-prescription, and herbal medications that your child may be taking. Please speak to your doctor or pharmacist before starting this medication. You should also make sure they are aware anytime you add a new prescription or non-prescription drug. If you have any questions regarding other medications, talk to your doctor or pharmacist.
How is Epidiolex given?	It is given twice daily and is dosed based on your child's weight. It is important that Epidiolex be given consistently with meals and given around the same time each day.
Can Epidiolex be given with food?	Although Epidiolex can be given with or without food, it is preferred that it be given with meals.
Can Epidiolex be administered through a gastrostomy (G-tube)?	Yes; however, the G-tube should be flushed well. Give Epidiolex first, followed with water, then give some formula, and follow with water to flush the G-tube well. Please discuss this with your physician. (Greenwich Biosciences Inc., written communication, June 12, 2019).
Is Epidiolex compatible with my child's ketogenic diet?	Yes. It may be given to your child if they are on the ketogenic diet. You should discuss with your doctor, dietitian, or pharmacist about your dietary therapies and any changes before starting Epidiolex.
What are the most common side effects of Epidiolex that my child may experience?	The most common reported side effects include drowsiness, diarrhea, decreased appetite, lack of energy, sleep problems, increased liver enzymes, and infections.
Can my child overdose on Epidiolex?	As with any medication, overdoses or taking more than prescribed by your child's doctor can be harmful. If you suspect an overdose, accidental or not, please call your physician or poison control at (800) 222-1222.
Where can I get Epidiolex?	Epidiolex is only dispensed through specialty pharmacies. Someone from the pharmacy will verify your child's prescription and work with your insurance company.
Will medical insurance cover Epidiolex?	Yes, most plans do. There is an approval process that can take days to a few weeks. It is approved for patients 2 years and older with a diagnosis of Lennox-Gastaut syndrome or Dravet syndrome.
Is there financial or patient support for Epidiolex?	The manufacturer has a support program. "Epidiolex Engage" includes an Epidiolex Copay Savings Program. Talk to your doctor or pharmacist should you have any concerns about affording your medications. https://www.epidiolex.com/engage-patient-support/assistance

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considered phytocannabinoids, which are chemicals within cannabis that may interact with the cannabinoid receptor.^{5,6} Although the exact mechanism of action is unknown, both CBD and THC are thought to be efficacious in their role for pediatric epilepsy.^{5,6} Using the non-psychoactive component, CBD, allows patients to have few side psychoactive side effects while still having the benefit of reduction in seizure frequency.⁶ There are other cannabidiol products currently on the

market, including hemp oil. Hemp oil is federally legal and contains less than or equal to 0.3% THC and is hemp derived. It can be bought over the counter at pharmacies, grocery stores, and even gas stations.⁷ Some states allow patients or caregivers to possess CBD products greater than 5% with a state permit.⁷ Although it is becoming increasingly common to see patients on hemp oil because of the ease of access, it is important to recognize that none of these products

are FDA approved and have efficacy data in relation to seizures.⁷ The FDA has released a statement saying it is “aware that some companies are marketing products containing cannabis and cannabis-derived compounds in ways that violate the Federal Food, Drug and Cosmetic Act (FD&C Act) and that may put the health and safety of consumers at risk.”⁸ The Table below contains a list of frequently asked questions regarding Epidiolex.

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