



Charles, age 43 | Individual living with LGS and intellectual and developmental disabilities (IDD)

INDICATIONS & IMPORTANT SAFETY INFORMATION

INDICATIONS:

EPIDIOLEX (cannabidiol) oral solution is indicated for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS), or tuberous sclerosis complex (TSC) in patients 1 year of age and older.

CONTRAINDICATION: HYPERSENSITIVITY

EPIDIOLEX (cannabidiol) oral solution is contraindicated in patients with a history of hypersensitivity to cannabidiol or any ingredients in the product.

Please see additional Important Safety Information throughout and full Prescribing Information.

 **Epidiolex**[®]
(cannabidiol)
Discover the Possibilities

An AED unlike any other—the first and only FDA-approved cannabidiol



Charles, age 43 | EPIDIOLEX patient living with LGS

EPIDIOLEX has broad-spectrum efficacy, significantly reducing multiple seizure types across 3 of the most difficult-to-treat epilepsies¹⁻³



Demonstrated reductions in:

- TSC-associated seizures, including both partial-onset* and generalized seizures
- Drop/total seizures in LGS
- Convulsive seizures in Dravet syndrome



Studied in patients on a wide range of concomitant treatments, EPIDIOLEX can be used as a monotherapy or with other AEDs



The **only** medication indicated to treat seizures associated with TSC, LGS, and Dravet syndrome

*Partial-onset seizures (focal) included simple partial seizures (focal motor seizure), complex partial seizures (focal impaired), and secondary generalized tonic-clonic seizures (focal to bilateral tonic-clonic).⁴

AEDs=antiepileptic drugs; LGS=Lennox-Gastaut syndrome; TSC=tuberous sclerosis complex.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS & PRECAUTIONS

Hepatocellular Injury:

EPIDIOLEX can cause dose-related transaminase elevations. Concomitant use of valproate and elevated transaminase levels at baseline increase this risk. Transaminase and bilirubin levels should be obtained prior to starting treatment, at one, three, and six months after initiation of treatment, and periodically thereafter, or as clinically indicated.

Please see additional Important Safety Information throughout and full Prescribing Information.

Ready to prescribe EPIDIOLEX?



Flexible dosing for tolerability and response optimization



Eligible for insurance coverage



In all 3 indications, EPIDIOLEX was found to have a consistent safety profile in children and adults.



Not a federally scheduled drug

The most common adverse reactions in patients receiving EPIDIOLEX ($\geq 10\%$ and greater than placebo) include:

- Transaminase elevations
- Somnolence
- Decreased appetite
- Diarrhea
- Pyrexia
- Vomiting
- Fatigue, malaise, and asthenia
- Rash
- Insomnia, sleep disorder, and poor-quality sleep
- Infections



For assistance in ordering EPIDIOLEX, please email LTCsupport@greenwichbiosciences.com or call 1-833-745-8384

For general inquiries regarding EPIDIOLEX, call Greenwich Biosciences Medical Information at 1-833-GBIOSCI (1-833-424-6724).

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS & PRECAUTIONS (CONT'D)

Hepatocellular Injury: (Cont'd)

Resolution of transaminase elevations occurred with discontinuation of EPIDIOLEX, reduction of EPIDIOLEX and/or concomitant valproate, or without dose reduction. For patients with elevated transaminase levels, consider dose reduction or discontinuation of EPIDIOLEX or concomitant medications known to affect the liver (e.g., valproate or clobazam). Dose adjustment and slower dose titration is recommended in patients with moderate or severe hepatic impairment. Consider not initiating EPIDIOLEX in patients with evidence of significant liver injury.

Please see additional Important Safety Information throughout and full Prescribing Information.

 **Epidiolex**[®]
(cannabidiol)

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS & PRECAUTIONS (CONT'D)

Somnolence and Sedation:

EPIDIOLEX can cause somnolence and sedation that generally occurs early in treatment and may diminish over time; these effects occur more commonly in patients using clobazam and may be potentiated by other CNS depressants.

Suicidal Behavior and Ideation:

Antiepileptic drugs (AEDs), including EPIDIOLEX, increase the risk of suicidal thoughts or behavior. Inform patients, caregivers, and families of the risk and advise to monitor and report any signs of depression, suicidal thoughts or behavior, or unusual changes in mood or behavior. If these symptoms occur, consider if they are related to the AED or the underlying illness.

Withdrawal of Antiepileptic Drugs:

As with most AEDs, EPIDIOLEX should generally be withdrawn gradually because of the risk of increased seizure frequency and status epilepticus.

ADVERSE REACTIONS:

The most common adverse reactions in patients receiving EPIDIOLEX ($\geq 10\%$ and greater than placebo) include transaminase elevations; somnolence; decreased appetite; diarrhea; pyrexia; vomiting; fatigue, malaise, and asthenia; rash; insomnia, sleep disorder and poor-quality sleep; and infections. Hematologic abnormalities were also observed.

PREGNANCY:

EPIDIOLEX should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Encourage women who are taking EPIDIOLEX during pregnancy to enroll in the North American Antiepileptic Drug (NAAED) Pregnancy Registry.

DRUG INTERACTIONS:

Strong inducers of CYP3A4 and CYP2C19 may affect EPIDIOLEX exposure. EPIDIOLEX may affect exposure to CYP2C19 substrates (e.g., clobazam, diazepam, stiripentol), orally administered P-gp substrates, or other substrates (see full Prescribing Information). Consider dose reduction of orally administered everolimus, with appropriate therapeutic drug monitoring, when everolimus is combined with EPIDIOLEX. A lower starting dose of everolimus is recommended when added to EPIDIOLEX therapy. Concomitant use of EPIDIOLEX and valproate increases the incidence of liver enzyme elevations. Pneumonia was observed more frequently with concomitant use of EPIDIOLEX and clobazam. Dosage adjustment of EPIDIOLEX or other concomitant medications may be necessary.

Please see EPIDIOLEX full [Prescribing Information](#) for additional important information.

References: **1.** Wirrell EC. *Can J Neurol Sci.* 2016;43(suppl 3):S13-S18. **2.** Piña-Garza JE, Boyce D, Tworek DM, et al. *Epilepsy Behav.* 2019;90:148-153. **3.** Song J, Swallow E, Said Q, et al. *J Neurol Sci.* 2018;391:104-108. **4.** Fisher RS, Cross JH, French JA, et al. *Epilepsia.* 2017;58(4):522-530.