

EPIDIOLEX[®] (cannabidiol) is available for use at long- term care (LTC) facilities, including group homes and intermediate care facilities

EPIDIOLEX is FDA approved and can be prescribed by any licensed practitioner and filled through any facility-affiliated LTC pharmacy or local specialty pharmacy, just like every other prescription epilepsy medication. As an FDA-approved drug, EPIDIOLEX may be lawfully prescribed and is a federally non-controlled prescription medicine.



Charles, age 43 | EPIDIOLEX resident living in a group home facility

EPIDIOLEX is available in LTC pharmacies

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

If no pharmacy is associated with the LTC facility, EPIDIOLEX is available in local specialty pharmacies. Ask your Neurology Account Manager for a list of authorized specialty pharmacies.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATION: HYPERSENSITIVITY

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

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. 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.

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.

Please see additional Important Safety Information on reverse and full [Prescribing Information](#).

 **Epidiolex[®]**
(cannabidiol)



EPIDIOLEX[®] (cannabidiol) is an AED unlike any other—the first and only FDA-approved cannabidiol

EPIDIOLEX is the only treatment indicated for seizures associated with **TSC, LGS, and Dravet syndrome in patients 1 year and older.**



Structurally distinct from other AEDs and can be prescribed in adults and children as early as 1 year of age across 3 indications



Demonstrated significant reductions in TSC-associated seizures, including both partial-onset* and generalized seizures; drop/total seizures in LGS; and convulsive seizures in Dravet syndrome



Offers flexible dosing for tolerability and response optimization



Eligible for insurance coverage

For general inquiries regarding EPIDIOLEX, call Jazz Pharmaceuticals Medical Information at 1-833-424-6724

*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).¹

IMPORTANT SAFETY INFORMATION & INDICATIONS (CONT'D)

WARNINGS & PRECAUTIONS

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.

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.

Please refer to the EPIDIOLEX full Prescribing Information for additional important information.

Reference: 1. Fisher RS, Cross JH, French JA, et al. *Epilepsia*. 2017;58(4):522-530.

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

