

Available for order by long-term care pharmacies



What is EPIDIOLEX® (cannabidiol)?

EPIDIOLEX is a prescription medicine used to treat seizures associated with Lennox-Gastaut syndrome (LGS), Dravet syndrome, or tuberous sclerosis complex (TSC) in patients 1 year of age and older. EPIDIOLEX is the first and only FDA-approved cannabidiol (CBD) and is only available by prescription.

Important Safety Information

EPIDIOLEX is contraindicated in patients with a history of hypersensitivity to cannabidiol or any ingredients in the product. For information on Warnings and Precautions and recommendations on liver monitoring, please see Important Safety Information on reverse side and full [Prescribing Information](#).



How is EPIDIOLEX ordered?

For long-term care pharmacies, EPIDIOLEX can be ordered through the following specialty distributors:

Cardinal Health Specialty Distribution	CuraScript Specialty Distribution	McKesson US Pharmaceutical
Email: GMB-SPD-CSOrderEntry@cardinalhealth.com Phone: 1-866-677-4844 Online portal (for current accounts): https://specialtyonline.cardinalhealth.com	Email: Customer.Service@curascript.com Phone: 1-877-599-7748 Fax: 1-800-862-6208	Phone: 1-855-625-7385 Website: https://connect.mckesson.com

If you are an AmerisourceBergen customer, place your orders through ABC Order, item #10232069, or by calling Customer CARE at 1-844-222-2273.

How is EPIDIOLEX dosed?	
Starting dose	The recommended starting dose of EPIDIOLEX is 2.5 mg/kg taken twice daily (5 mg/kg/day) for 1 week.
Titration	After 1 week's treatment, your patient's dose can be increased in weekly increments of 5 mg/kg/day (2.5 mg/kg twice daily). For patients in whom a more rapid titration is warranted, the dosage may be increased no more frequently than every other day.
Recommended maintenance doses	For patients with LGS and Dravet syndrome, the recommended maintenance dose is 5 mg/kg twice daily (10 mg/kg/day) to a maximum (if tolerated and required) of 10 mg/kg twice daily (20 mg/kg/day). In these patients, administration of the 20 mg/kg/day dosage resulted in somewhat greater reductions in seizure rates than the recommended maintenance dosage of 10 mg/kg/day, but with an increase in adverse reactions. For patients with TSC, the recommended maintenance dose is 25 mg/kg/day. The effectiveness of doses lower than 25 mg/kg/day has not been studied in patients with TSC. Visit EPIDIOLEXhcp.com for a dosing calculator.

Dosage adjustment is recommended for patients with moderate or severe hepatic impairment.

How is EPIDIOLEX supplied and stored?	
Dosage form	100 mg/mL oral solution
Supplied	EPIDIOLEX is a strawberry flavored clear, colorless to yellow solution supplied in an amber glass bottle with a child-resistant closure containing 100 mL or 60 mL of oral solution. The EPIDIOLEX kit contains 1 amber bottle, 1 adapter, and 2 calibrated dosing syringes. Additional dosing syringes can be ordered free of charge upon request. NDC 70127-100-10 EPIDIOLEX 100 mL kit NDC 70127-100-60 EPIDIOLEX 60 mL kit
Storage and handling	Store EPIDIOLEX in an upright position at 20°C to 25°C (68°F to 77°F). Do not freeze. Use within 12 weeks of first opening the bottle, then discard any remainder.

How much does EPIDIOLEX cost?

The WAC as of January 2021 is **\$1,420 per 100 mL bottle and \$852 per 60 mL bottle**. For either bottle of EPIDIOLEX, the WAC is **\$14.20 per mL**. This price is subject to change and other factors may affect the price charged.¹

When will my order arrive?

Orders with an established account (including license and controlled substance detail on file) typically deliver within 1 to 2 business days.

For general inquiries regarding EPIDIOLEX® (cannabidiol), call Greenwich Biosciences Medical Information at 1-833-GBIOSCI (1-833-424-6724). For assistance in ordering EPIDIOLEX, please email LTCsupport@greenwichbiosciences.com, or call 1-833-745-8384

IMPORTANT SAFETY INFORMATION & INDICATIONS

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.

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. Data on file. VV-MED-03211. 2021.