

## What is EPIDIOLEX® (cannabidiol)?

EPIDIOLEX is a prescription medicine used to treat seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older. EPIDIOLEX is the first FDA-approved medication consisting of highly purified, plant-derived cannabidiol (CBD).



What is the recommended dose of EPIDIOLEX?	
<b>Starting dose:</b>	The recommended starting dose of EPIDIOLEX is 2.5 mg/kg taken twice daily (5 mg/kg/day) for 1 week
<b>Titration:</b>	After 1 week's treatment, each dose should be increased weekly by 2.5 mg/kg administered twice daily (5 mg/kg/day) to a therapeutic dose of 5 mg/kg twice daily (10 mg/kg/day)
<b>Maximum dose:</b>	Based on individual clinical response and tolerability, each dose can be further increased in weekly increments up to 10 mg/kg twice daily (20 mg/kg/day)*

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

How is EPIDIOLEX supplied and stored?	
<b>Dosage form:</b>	100 mg/mL oral solution
<b>Supplied:</b>	EPIDIOLEX is supplied in a 105 mL amber glass bottle with child-resistant closure. EPIDIOLEX is a strawberry-flavored, clear, colorless-to-yellow solution. The EPIDIOLEX kit contains one 105 mL 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 kit
<b>Storage and handling:</b>	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 September 2018 is <b>\$1235/bottle</b> . This price is subject to change and other factors may affect the price charged.	

## How is EPIDIOLEX ordered?†

For hospitals and other non-retail institutions, EPIDIOLEX can be ordered through the following specialty distributors:

Cardinal Health Specialty Distribution	
	Email: <a href="mailto:GMB-SPD-CSOrderEntry@cardinalhealth.com">GMB-SPD-CSOrderEntry@cardinalhealth.com</a>
	Phone: <b>1-866-677-4844</b>
	Online portal (for current accounts): <a href="https://specialtyonline.cardinalhealth.com">https://specialtyonline.cardinalhealth.com</a>

CuraScript Specialty Distribution	
	Email: <a href="mailto:Customer.Service@curascript.com">Customer.Service@curascript.com</a>
	Phone: <b>1-877-599-7748</b>
	Fax: <b>1-800-862-6208</b>

†EPIDIOLEX is a Schedule V controlled substance. Customers must hold all required licenses and must be otherwise permitted by applicable law to purchase and distribute controlled substances. Customers may be required to provide related account set-up verifications prior to any orders being filled.

**Please see Important Safety Information on reverse side and accompanying full Prescribing Information.**

## 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.

## What if I'm a primary customer of another specialty distributor?

You can establish a new direct distribution account with Cardinal Health or CuraScript Specialty Distribution. If you have a valid license and controlled substance information on file, Cardinal Health may "courtesy bill" orders approved and submitted by your primary distributor.

McKesson customers can place orders via the following:

Call customer support at **1-855-625-6285**

For hospitals: Call **1-855-625-4677** or email **CustomerSupport\_Hospital@McKesson.com**

## Do you want to establish a new account with Cardinal Health Specialty Distribution?

Call **1-866-677-4844** to set up a new account.

## What patient support is available?

Greenwich Biosciences, Inc. has designed a comprehensive program called EPIDIOLEX Engage™ to help patients who have been prescribed EPIDIOLEX® (cannabidiol) access their medication for outpatient use. This program will assist with benefits verification, prior authorization support, and ongoing education and support to enable the best possible patient experience with EPIDIOLEX.

**For general questions or inquiries about EPIDIOLEX Engage, call 1-833-GBNGAGE (1-833-426-4243)**

### Indications

EPIDIOLEX is indicated for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS) in patients 2 years of age and older.

### Important Safety Information

**Contraindication: Hypersensitivity:** EPIDIOLEX 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 (≥10% and greater than placebo) include somnolence; decreased appetite; diarrhea; transaminase elevations; 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:** Moderate or strong inhibitors or inducers of CYP3A4 and CYP2C19 may affect EPIDIOLEX exposure. EPIDIOLEX may affect exposure to CYP2C19 substrates (e.g., clobazam, diazepam) or others. Concomitant use of EPIDIOLEX and valproate increases the incidence of liver enzyme elevations. Dosage adjustment of EPIDIOLEX or other concomitant medications may be necessary.

**Drug Abuse:** EPIDIOLEX is a Schedule V controlled substance and has a low potential for abuse.

**Please see accompanying full Prescribing Information for additional important information.**