



# Seizures are shared. So is relief.

When a seizure strikes, it hits the patient the hardest. But it also affects everything and everyone around them—especially caregivers.

The intense, around-the-clock commitment takes a toll on the family, so when medicines and other therapies fail to offer seizure reduction, it's not just disappointing, it's devastating.

Relief can be possible for both patients and caregivers with EPIDIOLEX® (cannabidiol) CV. The first and only treatment of its kind to reduce seizures in people living with Lennox-Gastaut syndrome (LGS) or Dravet syndrome.



#### **Select Important Safety Information**

EPIDIOLEX may cause liver problems. Your doctor may order blood tests to check your liver before you start taking EPIDIOLEX and during treatment. In some cases, EPIDIOLEX treatment may need to be stopped. Call your doctor right away if you start to have any of these signs and symptoms of liver problems during treatment with EPIDIOLEX:

- o loss of appetite, nausea, vomiting
- o fever, feeling unwell, unusual tiredness
- o yellowing of the skin or the whites of the eyes (jaundice)
- itching
- o unusual darkening of the urine
- o right upper stomach area pain or discomfort



EPIDIOLEX® (cannabidiol) CV is the first and only FDA-approved prescription CBD to treat seizures associated with LGS or Dravet in patients 2 years of age and older.

EPIDIOLEX is believed to work differently from other prescription seizure medicines, but the exact mechanisms of action (how it works) are unknown.

EPIDIOLEX went through the rigorous FDA-approval process to ensure it is consistent and stable, with a safety and efficacy profile that has been throughly evaluated.



# What's in EPIDIOLEX?

EPIDIOLEX contains a highly purified form of cannabidiol (CBD) that comes from the cannabis plant. The active ingredient is nearly 100% CBD.

EPIDIOLEX is made without sugar or carbohydrates, so it can be used with most epilepsy diets, such as the ketogenic diet. If you or your loved one are on a dietary therapy, talk to your doctor before taking EPIDIOLEX.



## How is EPIDIOLEX taken?

EPIDIOLEX is an oral solution that is taken twice daily. It should be administered consistently with respect to meals.

If you or your loved one has a gastrostomy tube (g-tube), there are special considerations. To learn more, please contact Greenwich Biosciences at 1-833-424-6724 (1-833-GBIOSCI) and talk to your doctor about your specific needs.

# Seizure Reduction With EPIDIOLEX



EPIDIOLEX significantly reduced seizures in patients with LGS and Dravet who had previously failed on multiple seizure medicines.

As a caregiver, you may find reassurance knowing that more than 500 LGS and Dravet patients took part in 3 clinical studies—the largest placebo-controlled, clinical study program in these conditions to date. Even after these trials were completed, the majority of patients continued taking EPIDIOLEX for more than a year.



### **DID YOU KNOW?**

EPIDIOLEX can be used in combination with your loved one's existing seizure therapies.\* This may help you and your doctor create a flexible treatment plan that offers greater seizure reduction.

\*Based on clinical studies in which 94% of patients with LGS and 93% of patients with Dravet were on 2 or more seizure medicines.

#### Select Important Safety Information

EPIDIOLEX may cause you to feel sleepy, which may get better over time. Other medicines (e.g., clobazam) or alcohol may increase sleepiness. Do not drive, operate heavy machinery, or do other dangerous activities until you know how EPIDIOLEX affects you.



## Fewer Seizures in Patients With LGS



### **EPIDIOLEX** significantly reduced drop seizures\*

Monthly drop-seizure reduction over the 14-week treatment period in Study 2

EPIDIOLEX (10 mg/kg/day dose) (20 mg/kg/day dose)

REDUCTION REDUCTION (20 mg/kg/day dose)

## 17% reduction in the placebo group

In Study 1, there was a 44% monthly reduction in drop seizures on 20 mg/kg/day dose of EPIDIOLEX compared to 22% on placebo.

#### With EPIDIOLEX, freedom from drop seizures is possible.

 4% of patients who took EPIDIOLEX 10 mg/kg/day and 7% who took EPIDIOLEX 20 mg/kg/day (compared to 1% on placebo) reported no drop seizures<sup>†</sup>

What were the most common medicines patients were taking during the trial?

Clobazam, valproate, levetiracetam, and lamotrigine.

What happened when the dose was increased?

At 20 mg/kg/day doses, there was a somewhat greater reduction in seizure rates than 10 mg/kg/day; however, there was also an increase in side effects.

more patients with LGS saw a 75% or greater reduction in their drop seizures with EPIDIOLEX 10 mg/kg/day (11%) compared to placebo (3%) in Study 2.

What did caregivers report about their loved one's response to EPIDIOLEX?

The majority of caregivers reported an improvement in their loved one's overall condition with EPIDIOLEX treatment.‡

Did patients continue to experience improved seizure control after the trial?

Patients who stayed on EPIDIOLEX after the initial trial maintained seizure reduction in a 72-week open-label phase.

#### Select Important Safety Information

Like other antiepileptic drugs, EPIDIOLEX may cause suicidal thoughts or actions in a very small number of people, about 1 in 500. Call a healthcare provider right away if you have any signs of depression or anxiety, thoughts about suicide or self-harm, feelings of agitation or restlessness, aggression, irritability, or other unusual changes in behavior or mood, especially if they are new, worse, or worry you.



<sup>\*</sup>Drop seizures include several seizure types: tonic, atonic, and tonic-clonic that led, or could have led, to a fall or injury.

<sup>†</sup>During the 12-week maintenance period.

<sup>&</sup>lt;sup>‡</sup>Patients/caregivers reported improvement on the Subject/Caregiver Global Impression of Change (S/CGIC) scale, which is a 7-point scale that ranges from "Very Much Improved" to "Very Much Worse," evaluating patient or caregiver assessment of the patient's overall condition from the beginning of the study to the end of the study.

## Fewer Seizures in Patients With Dravet



### EPIDIOLEX significantly reduced convulsive seizures\*

Monthly convulsive-seizure reduction over the 14-week treatment period

EPIDIOLEX (20 mg/kg/day dose)



**REDUCTION** 

**VS** 

## 13% reduction in the placebo group

### With EPIDIOLEX, freedom from convulsive seizures is possible.

o 7% who took EPIDIOLEX 20 mg/kg/day (compared to 0 patients taking placebo) reported no convulsive seizures<sup>†</sup>

What were the most common medicines patients were taking during the trial?

Clobazam, valproate, and stiripentol.

What is the recommended dose?

10 mg/kg/day as a maintenance dose and 20 mg/kg/day as a maximum dose.

# 2x

more patients with Dravet saw a 75% or greater reduction in their convulsive seizures with EPIDIOLEX 20 mg/kg/day (23%) compared to placebo (12%).

What did caregivers report about their loved one's response to EPIDIOLEX?

The majority of caregivers reported an improvement in their loved one's overall condition with EPIDIOLEX treatment.<sup>‡</sup>

Did patients continue to experience improved seizure control after the trial?

Patients who stayed on EPIDIOLEX after the initial trial maintained seizure reduction in a 72-week open-label phase.

#### **Select Important Safety Information**

Take EPIDIOLEX exactly as your healthcare provider tells you. Do not stop taking EPIDIOLEX without first talking to your healthcare provider. Stopping a seizure medicine suddenly can cause serious problems.



<sup>\*</sup>Convulsive seizures include several seizure types: tonic, tonic-clonic, atonic, and clonic.

<sup>†</sup>During the 12-week maintenance period.

<sup>&</sup>lt;sup>‡</sup>Patients/caregivers reported improvement on the Subject/Caregiver Global Impression of Change (S/CGIC) scale, which is a 7-point scale that ranges from "Very Much Improved" to "Very Much Worse," evaluating patient or caregiver assessment of the patient's overall condition from the beginning of the study to the end of the study.



# EPIDIOLEX From Greenwich Biosciences

Cannabidiol (CBD) is the active ingredient in EPIDIOLEX® (cannabidiol) CV, a prescription medicine approved by the FDA.





## **DID YOU KNOW?**

EPIDIOLEX will not make you feel "high," the common effect associated with THC. EPIDIOLEX and THC are entirely different from each other and have different effects on the body.

#### **Select Important Safety Information**

The most common side effects of EPIDIOLEX include sleepiness, decreased appetite, diarrhea, increase in liver enzymes, feeling very tired and weak, rash, sleep problems, and infections.



The active ingredient in EPIDIOLEX comes directly from cannabis plants, which produce CBD. EPIDIOLEX is not synthetic (made in a lab).



## From the ground up

Each cannabis plant we use is grown in its own container with controlled light, water, and soil, in our highly regulated, state-of-the-art greenhouses.



## Manufactured to meet the high standards of the FDA

EPIDIOLEX is made according to the World Health Organization's Good Agriculture Practices, the FDA's Current Good Manufacturing Practices, and other strict regulations. For dispensary or online products, there are no federal standards (eg, quality, consistency, CBD concentration), and regulations vary by state.



## The FDA difference

EPIDIOLEX went through the rigorous FDA-approval process to ensure it is consistent and stable, with a safety and efficacy profile that has been thoroughly evaluated. You can only get FDA-approved medicines like EPIDIOLEX through a doctor's prescription and at the pharmacy—not a dispensary or online.

In fact, studies conducted by the FDA and other researchers found that several dispensary and online CBD products did not have the levels of CBD they claimed.\*† However, every bottle of EPIDIOLEX has the exact ingredients listed on the package, ensuring consistent concentrations of CBD with every batch and delivering quality that meets FDA standards.

<sup>\*</sup>Source: https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm484109.htm.
†Source: Vandrey R, Raber JC, Raber ME, Douglass B, Miller C,
Bonn-Miller MO. Cannabinoid dose and label accuracy in edible
medical cannabis products. *JAMA*. 2015;313(24):2491-2493.



# Key Things to Know About EPIDIOLEX



EPIDIOLEX may cause liver problems. Your doctor may order blood tests to check your liver before you start taking EPIDIOLEX and during treatment. In some cases, EPIDIOLEX treatment may need to be stopped. Call your doctor right away if you start to have any of these signs and symptoms of liver problems during treatment with EPIDIOLEX:

- o loss of appetite, nausea, vomiting
- o fever, feeling unwell, unusual tiredness
- o yellowing of the skin or the whites of the eyes (jaundice)
- o itching
- o unusual darkening of the urine
- o right upper stomach area pain or discomfort

Your doctor may also order blood tests to monitor for other side effects.



## Does EPIDIOLEX interact with my other medicines?

O EPIDIOLEX may interact with some seizure medicines or other medicines you are taking. Do not start or stop other medicines without talking to your doctor. Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, herbal supplements, and cannabis-based products



## What are the possible side effects of EPIDIOLEX?

- The most common side effects are sleepiness, decreased appetite, diarrhea, increase in liver enzymes, feeling very tired and weak, rash, sleep problems, and infections
- Many side effects cleared up within 4 weeks of onset, and most resolved throughout the 14-week study
- O Adverse reactions were similar across LGS and Dravet in pediatric and adult patients
- O In controlled studies, the rate of discontinuation (patients who stopped taking the medicine) for any adverse event was 1% for patients taking placebo and 3% for patients taking EPIDIOLEX 10 mg/kg/day. For patients taking EPIDIOLEX 20 mg/kg/day, the rate of discontinuation for any adverse event was 12%
- The most frequent causes of discontinuation were increase in liver enzymes and sleepiness
- EPIDIOLEX can cause weight loss
- O Your doctor may also order blood tests to look out for other side effects
- These are not all the possible side effects of EPIDIOLEX. For more information, ask your healthcare provider or pharmacist



EPIDIOLEX may cause you to feel sleepy, which may get better over time. Other medicines (eg, clobazam) or alcohol may increase sleepiness. Do not drive, operate heavy machinery, or do other dangerous activities until you know how EPIDIOLEX affects you.



## Who should not take EPIDIOLEX?

 Do not take EPIDIOLEX if you are allergic to cannabidiol or any of the ingredients in EPIDIOLEX





# Support With EPIDIOLEX ENGAGE™



Living with serious and rare conditions like LGS and Dravet is tough, so helpful resources can make a big difference. When you become an *EPIDIOLEX ENGAGE*<sup>TM</sup> member, you'll receive practical tools, tips, and information.

## Go anywhere with EPIDIOLEX

No matter where you're going, keep EPIDIOLEX safe, secure, and by your side. Your travel case includes space for your medication bottle and 2 syringes. Use the sleeve to keep your prescription slip, travel card, and any seizure care instructions handy.





## Stay on track

Get resources, worksheets, and tools, including a seizure tracker and medication schedule.



## Hear from fellow caregivers

Receive tips and guidance for living with LGS and Dravet syndrome.

Sign up at epidiolexonthego.com

# Patients with an EPIDIOLEX prescription may be eligible to receive:

The EPIDIOLEX Copay Savings Program, which may offer the first 30 days of EPIDIOLEX for as low as \$0 and refills for as low as \$25 per month.

The program is only for commercially insured EPIDIOLEX patients with a legal residence in the United States.

Qualifying patients may receive up to \$2,600 annually to help meet copay costs. Eligibility criteria and terms and conditions apply.\*

Copay savings are applied directly at the pharmacy, so there is no need to worry about whether you have your card or if it's expired.



The Patient Assistance Program (PAP) is available for eligible patients with no insurance or not enough insurance to cover their prescription. Eligibility assessed on an individual basis.



We know insurance coverage may seem complex, but the *EPIDIOLEX ENGAGE*  $^{\text{TM}}$  Support Team is here to help with things like insurance verification.



Free shipping directly to your home.

For more information about paying for your medicine, call 1-833-GBNGAGE/1-833-426-4243.

Customer service associates are available Monday through Friday, 8:00 AM – 8:00 PM ET (excluding holidays).







## Support along the journey

If you learn that you or your loved one is living with LGS or Dravet, there are many resources available where you can find invaluable information, take advantage of support programs, have opportunities to connect with other caregivers, and much more.

You can also learn more about planning for potential changes in care as your loved one transitions into adulthood.

#### Find out more here:



#### Indications & Important Safety Information

#### What is EPIDIOLEX?

EPIDIOLEX is a prescription medicine that is used to treat seizures associated with LGS or Dravet in patients 2 years of age and older. It is not known if EPIDIOLEX is safe and effective in children under 2 years of age.

#### What is the Most Important Information I Should Know About EPIDIOLEX?

Do not take if you are allergic to cannabidiol or any of the ingredients in EPIDIOLEX. EPIDIOLEX may cause liver problems. Your doctor may order blood tests to check your liver before you start taking EPIDIOLEX and during treatment. In some cases, EPIDIOLEX treatment may need to be stopped. Call your doctor right away if you start to have any of these signs and symptoms of liver problems during treatment with EPIDIOLEX: loss of appetite, nausea, vomiting • fever, feeling unwell, unusual tiredness • yellowing of the skin or the whites of the eyes (jaundice) • itching • unusual darkening of the urine • right upper stomach area pain or discomfort.

EPIDIOLEX may cause you to feel sleepy, which may get better over time. Other medicines (e.g., clobazam) or alcohol may increase sleepiness. Do not drive, operate heavy machinery, or do other dangerous activities until you know how EPIDIOLEX affects you. Like other antiepileptic drugs, EPIDIOLEX may cause suicidal thoughts or actions in a very small number of people, about 1 in 500. Call a healthcare provider right away if you have any signs of depression or anxiety, thoughts about suicide or self-harm, feelings of agitation or restlessness, aggression, irritability, or other unusual changes in behavior or mood, especially if they are new, worse, or worry you. Take EPIDIOLEX exactly as your healthcare provider tells you. Do not stop taking EPIDIOLEX without first talking to your healthcare provider. Stopping a seizure medicine suddenly can cause serious problems.

#### What Else Should I Know When Taking EPIDIOLEX?

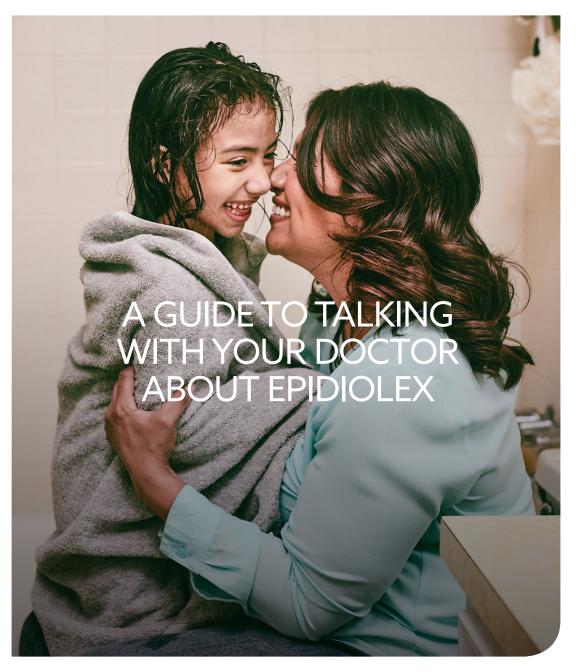
The most common side effects of EPIDIOLEX include sleepiness, decreased appetite, diarrhea, increase in liver enzymes, feeling very tired and weak, rash, sleep problems, and infections. EPIDIOLEX may affect the way other medicines work, and other medicines may affect how EPIDIOLEX works. Do not start or stop other medicines without talking to your healthcare provider. Tell healthcare providers about all the medicines you take, including prescription and over-the-counter medicines, vitamins, herbal supplements, and cannabis-based products. EPIDIOLEX is a federally controlled substance (CV) because it has a low potential for abuse. Keep EPIDIOLEX in a safe place to prevent theft, misuse, or abuse.

#### What Additional Information Applies to Women?

If you are pregnant or plan to become pregnant, EPIDIOLEX may harm your unborn baby. You and your healthcare provider will have to decide if you should take EPIDIOLEX while you are pregnant. If you become pregnant while taking EPIDIOLEX, talk to your healthcare provider about registering with the North American Antiepileptic Drug Pregnancy Registry (by calling 1-888-233-2334). The purpose of this registry is to collect information about the safety of antiepileptic medicines during pregnancy. Because many medicines like EPIDIOLEX are passed into breast milk, talk to your healthcare provider about the best way to feed your baby while taking EPIDIOLEX. Please refer to the EPIDIOLEX Medication Guide and Instructions for Use for additional important information.

You are encouraged to report side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.





# **Discussion Guide**

You are encouraged to have an open conversation with your doctor about your treatment goals and current medicines. It is important in determining if EPIDIOLEX® (cannabidiol) CV may be a good fit with your treatment plan.

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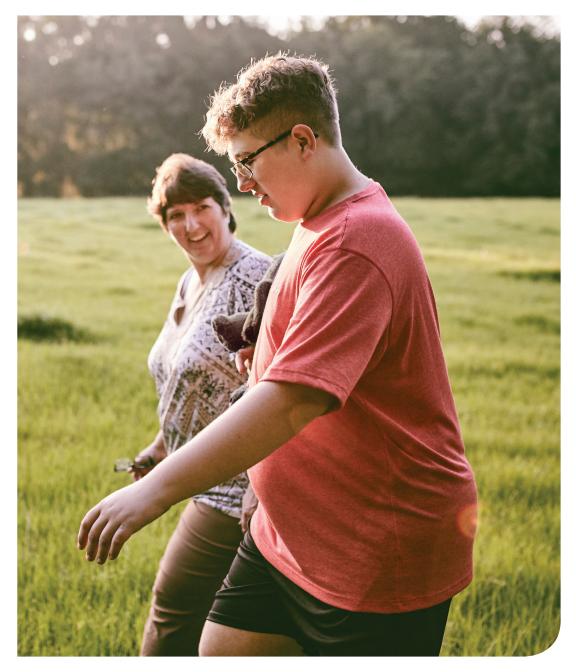
riere are some sample questions to ask your doctor.
1. How well are current medicines working?
2. Can an FDA-approved CBD (cannabidiol) be an effective and safe/tolerable treatment option for my loved one?
3. Is my loved one a candidate?
<b>4.</b> Can EPIDIOLEX be added to current medicines?



5. How is EPIDIOLEX different than cannabinoids currently being sold in dispensaries or online?
<b>6.</b> What amount of seizure reduction can I expect with EPIDIOLEX?
7. When could I begin to see results?

<b>8.</b> Are there any important considerations regarding safety of EPIDIOLEX or interactions with other medicines?
<b>9.</b> Can EPIDIOLEX be taken with current dietary therapy, ie, the ketogenic diet?





Additional notes and questions for your doctor	
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## Share the Relief With EPIDIOLEX



Reduces seizures associated with LGS and Dravet—even among those who have previously failed on multiple seizure medicines.



Was studied in more than 500 patients the largest placebocontrolled, clinical study program to date for LGS and Dravet.



Contains a highly purified form of cannabidiol (CBD) that comes from the cannabis plant. The active ingredient is nearly 100% CBD.



Is FDA approved to ensure quality and consistency in every bottle.

#### Select Important Safety Information

EPIDIOLEX may cause liver problems. Your doctor may order blood tests to check your liver before you start taking EPIDIOLEX and during treatment. In some cases, EPIDIOLEX treatment may need to be stopped. Call your doctor right away if you start to have any of these signs and symptoms of liver problems during treatment with EPIDIOLEX:

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- itching
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- o right upper stomach area pain or discomfort

Please see full Important Safety Information on page 17 of this brochure. Please refer to the Prescribing Information, including the Medication Guide and Instructions for Use, on EPIDIOLEX.com



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