

EPIDIOLEX is a prescription medicine that is used to treat seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex in patients 1 year of age and older.

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

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

Please see Important Safety Information throughout this brochure.



### Seizures are shared. Now hope is too.

Families share everything. For many, that includes the fears and frustrations of living with seizures. But with seizure reduction from EPIDIOLEX, families can share something else. They can experience the relief of more moments like these and look forward to what may be next.





For the latest updates, information, and stories about EPIDIOLEX, visit us on **Facebook @EPIDIOLEX** and subscribe at **youtube.com/EPIDIOLEX** 

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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
- 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



### Why EPIDIOLEX?



Proven to reduce seizures in people living with Lennox-Gastaut syndrome (LGS), Dravet syndrome, or tuberous sclerosis complex (TSC).



Can be taken by itself or in combination with other commonly prescribed seizure medicines.



Can be used to treat children as young as 1 year of age.

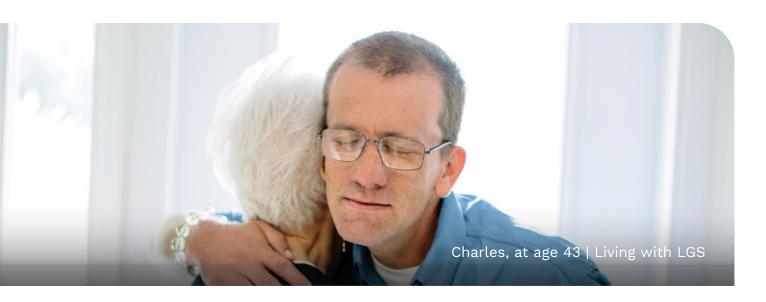


Safety evaluated across 4 studies involving more than 700 people.



The first and only FDA-approved prescription cannabidiol (CBD) medicine.

More than 15,000 people have been treated with EPIDIOLEX. **See their stories of hope at EPIDIOLEX.com** 



#### **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.





# EPIDIOLEX was proven to significantly reduce seizures in people living with LGS, Dravet syndrome, or TSC

When it comes to determining how well a medicine works to treat seizures, clinical trials are considered the gold standard. So you may find it reassuring to know that more than 500 people living with LGS or Dravet syndrome, and more than 200 people living with TSC, took part in the EPIDIOLEX studies. That's more than 700 people all together. As of 2020, EPIDIOLEX had the largest clinical study program across these conditions to date.

EPIDIOLEX significantly reduced seizures in people living with LGS, Dravet syndrome, or TSC for whom multiple previous seizure medicines did not work well.

Even after these studies were completed, many people continued to have fewer seizures when they went on to participate in longer-term studies.



#### Did you know?

EPIDIOLEX can be used by itself or in combination with existing seizure therapies. This may help you and your doctor create a flexible treatment plan that offers greater seizure reduction.

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

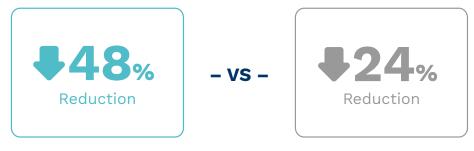
Like other antiepileptic drugs, EPIDIOLEX may cause suicidal thoughts or actions in a very small number of people, about 1 in 500. Call a healthcare provider right away if you have any signs of depression or anxiety, thoughts about suicide or self-harm, feelings of agitation or restlessness, aggression,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



#### Fewer seizures in people living with TSC

## EPIDIOLEX reduced the frequency of seizures in TSC by half

Reduction in TSC-associated seizures\* over the 16-week treatment period.



**EPIDIOLEX** 

25-mg/kg/day dose

In the placebo group

#### With EPIDIOLEX, freedom from seizures is possible for some

5% of people taking EPIDIOLEX achieved freedom from TSC-associated seizures (compared with 0% of people taking placebo).

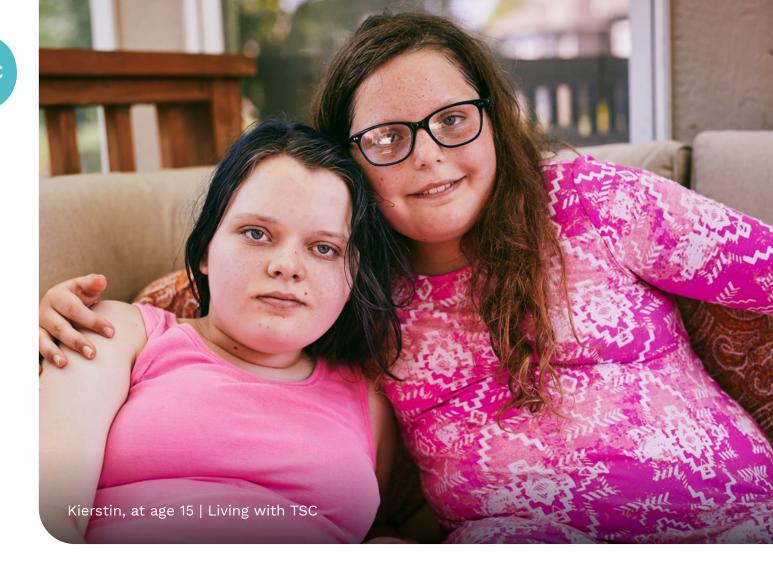
\*TSC-associated seizures included different types of partial onset (focal) seizures and generalized seizures.



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

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





#### Substantial reduction in TSC seizures with EPIDIOLEX

More people reduced their TSC seizures by 75% or more with EPIDIOLEX 25 mg/kg/day (19%), compared with 0% of people taking placebo.

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

#### **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.



#### Fewer seizures in people living with LGS

## EPIDIOLEX significantly reduced drop seizures in people living with LGS

Monthly drop-seizure\* reduction over the 14-week treatment period.







- VS -

**EPIDIOLEX** 

10-mg/kg/day dose

**EPIDIOLEX** 

20-mg/kg/day dose

In the placebo group

In another study, there was a 44% monthly reduction in drop seizures among people taking EPIDIOLEX in the 20-mg/kg/day group, compared with a 22% reduction taking placebo.

#### With EPIDIOLEX, freedom from drop seizures is possible for some

- 4% of people taking EPIDIOLEX 20 mg/kg/day (compared with 0% of people taking placebo) reported no drop seizures
- o In another study, 4% of people taking EPIDIOLEX 10 mg/kg/day and 7% taking EPIDIOLEX 20 mg/kg/day (compared with 1% of people taking placebo) reported no drop seizures<sup>†</sup>

\*Drop seizures included tonic, atonic, and tonic-clonic that led, or could have led, to a fall or injury.

†During the 12-week maintenance period.

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

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.





more people living with LGS saw a substantial reduction of 75% or greater in their drop seizures with EPIDIOLEX 10 mg/kg/day (11%), compared with placebo (3%).

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

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

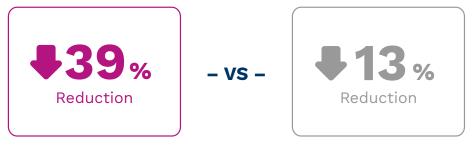
If you are pregnant or plan to become pregnant, EPIDIOLEX may harm your unborn baby. You and your healthcare provider will have to decide if you should take EPIDIOLEX while you are pregnant.



#### Fewer seizures in people living with Dravet syndrome

## EPIDIOLEX reduced convulsive seizures in people living with Dravet syndrome

Monthly convulsive-seizure\* reduction over the 14-week treatment period.



**EPIDIOLEX** 

20-mg/kg/day dose

In the placebo group

## With EPIDIOLEX, freedom from convulsive seizures is possible for some

o 7% of people taking EPIDIOLEX 20 mg/kg/day (compared with 0% of people taking placebo) reported no convulsive seizures<sup>†</sup>

\*Convulsive seizures included tonic, tonic-clonic, atonic, and clonic.

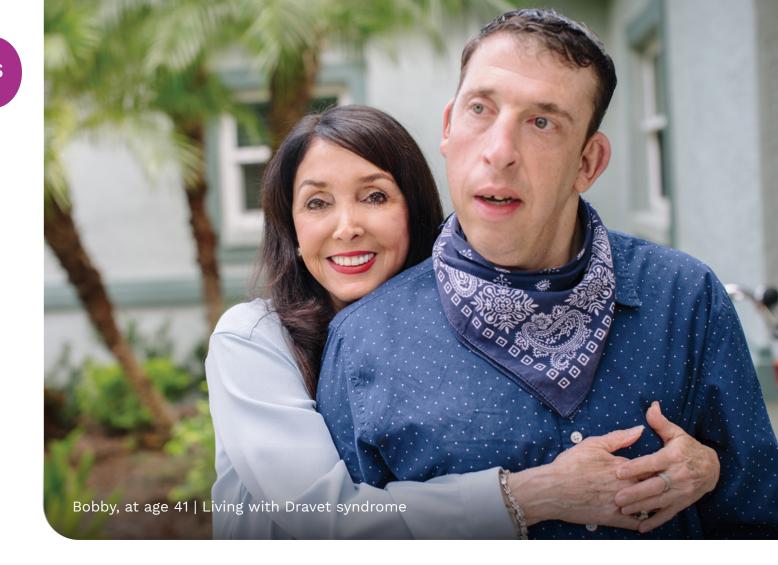
<sup>†</sup>During the 12-week maintenance period.



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

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.





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more people living with Dravet syndrome saw a substantial reduction of 75% or greater in their convulsive seizures with EPIDIOLEX 20 mg/kg/day (23%), compared with placebo (12%).

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

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

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.



## Key things to know about EPIDIOLEX



## 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:

- o loss of appetite, nausea, vomiting
- o fever, feeling unwell, unusual tiredness
- yellowing of the skin or the whites of the eyes (jaundice)
- o itching
- o 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.



## Key things to know about EPIDIOLEX



#### Does EPIDIOLEX interact with my other medicines?

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 other possible side effects of EPIDIOLEX?

- The most common side effects include increase in liver enzymes, sleepiness, decreased appetite, diarrhea, fever, vomiting, feeling very tired and weak, rash, sleep problems, and infections
- o Across studies in LGS, Dravet syndrome, and TSC, EPIDIOLEX was found to have a consistent safety profile in both children and adults
- o In the LGS and Dravet syndrome studies, the rate of discontinuation (patients who stopped taking the medicine) for any side effect 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 side effect was 12%
- In the TSC study, the rate of discontinuation for any side effect was 3% for patients taking placebo and 11% for patients taking EPIDIOLEX 25 mg/kg/day
- The most frequent causes of discontinuation were increase in liver enzymes and sleepiness in the LGS and Dravet syndrome studies, and rash in the TSC study
- o EPIDIOLEX can cause weight loss
- o Your doctor may also order blood tests to look out for other side effects
- o These are not all of the possible EPIDIOLEX side effects. For more information, ask your healthcare provider or pharmacist



## Experience the EPIDIOLEX difference



### The natural approach

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



Not genetically modified



No pesticides



No toxic heavy metals



No contaminants



#### What's in EPIDIOLEX?

EPIDIOLEX contains a highly purified form of 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 necessary, EPIDIOLEX can be administered via a feeding tube, such as a nasogastric tube (NG-tube) or gastrostomy tube (G-tube). Do not use with tubes made of polyvinyl chloride (PVC).

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## Experience the EPIDIOLEX difference

#### FDA 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, online, or hemp 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. EPIDIOLEX is the only FDA-approved CBD product and has been clinically studied in a comprehensive controlled trial program.

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.

\*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.

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- o itching
- o unusual darkening of the urine
- right upper stomach area pain or discomfort



## The EPIDIOLEX® Copay Savings Program

#### Savings made simple

The EPIDIOLEX® Copay Savings Program is expanding to better support eligible\* patients in response to the COVID-19 pandemic.

## No copay

for first-time prescriptions or refills filled between January 1, 2021 and December 31, 2021

## No limit

to the amount qualifying patients may receive to help meet copay costs during 2021

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

Take advantage of copay savings: Ask your specialty pharmacy about your eligibility for the copay savings program when they contact you.

This offer is subject to change or discontinuation without notice.

\*Eligibility criteria and terms and conditions apply. Please see **EPIDIOLEX.com/copay** for full terms and conditions, along with the latest program information.

<sup>†</sup>On January 1, 2022, the original copay program will resume where qualifying commercially insured patients will pay as low as \$0 for the first prescription and as low as \$25 for each additional 30-day prescription.



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 support program 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).



## EPIDIOLEX supports you every step of the way

Living with serious and rare conditions like LGS, Dravet syndrome, or TSC is tough, so helpful resources can make a big difference. When you become a member of the EPIDIOLEX support program, you'll receive practical tools, tips, and information.



## Sign up and get your free travel case

No matter where you're going, keep EPIDIOLEX safe, secure, and by your side.

#### Stay on track

Get resources, worksheets, and tools to help with your medicine, aid in travel, and more.

#### Hear from fellow caregivers

Receive tips and guidance for living with LGS, Dravet syndrome, or TSC.

#### Sign up at **EPIDIOLEX.com/support**

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#### **Important Safety Information & Indications**

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

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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 increase in liver enzymes, sleepiness, decreased appetite, diarrhea, fever, vomiting, 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.





#### **Important Safety Information & Indications (cont'd)**

#### **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.

#### What is EPIDIOLEX (cannabidiol)?

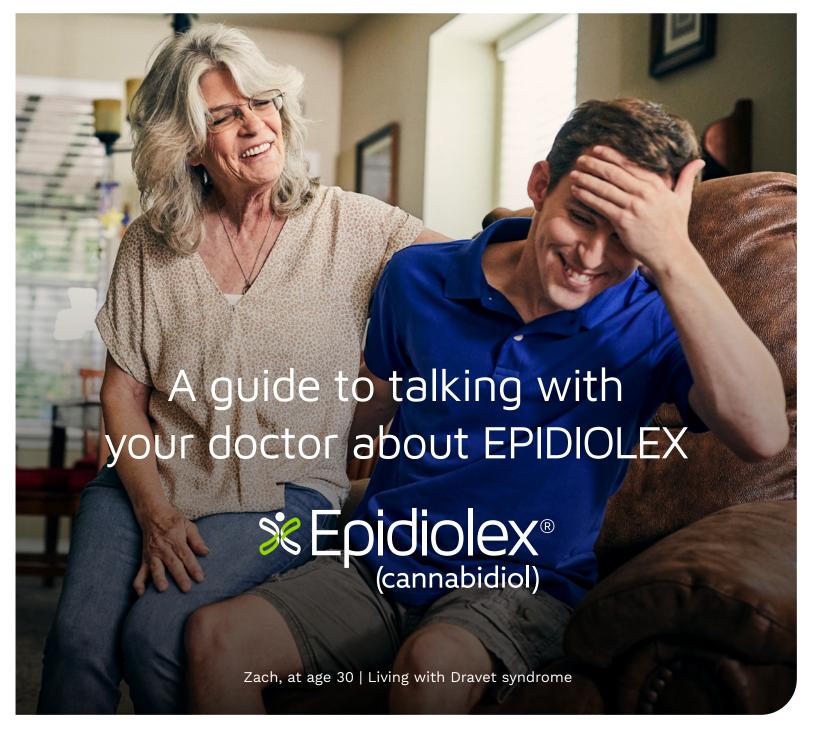
EPIDIOLEX is a prescription medicine that is used to treat seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex in patients 1 year of age and older. It is not known if EPIDIOLEX is safe and effective in children under 1 year of age.

Please refer to the EPIDIOLEX <u>Medication Guide</u> and <u>Instructions for Use</u> 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. You may also contact Greenwich Biosciences at 1-833-424-6724 (1-833-GBIOSCI).

Please click here for full <u>Prescribing Information</u>.





It's important to check in with your doctor about your current seizure medicines and ask yourself whether your treatment goals are still being met. These questions can help you have a conversation with your doctor about whether it's time to make a change—and whether EPIDIOLEX may be a good fit with your treatment plan.

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

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## Begin the EPIDIOLEX conversation

1.	These	are	the	seizure	medicines	that	are	currently	being	taken:

2	These ar	a tha	tynes	$\circ f$	ceizures	that ar	۵,	occurring	while	on these	e medicines:
Z.	mese an	e trie	types	ΟI	Seizures	liial ai	е	occurring	writte	on these	e mealtines.

**3.** While on these seizure medicines, seizures still happen:

☐ Rarely, if ever

☐ At least once a month

☐ Once or twice a week

☐ About once a day

☐ More than once a day

**5.** My goals for seizure treatment are:

**6.** My hopes for EPIDIOLEX are:

**7.** Additional notes and questions I have:

**4.** This is how satisfied I am with my current seizure medicines:

☐ Fairly satisfied

☐ Okay, needs improvement

 $\hfill \square$  It's time to try something different



## Ask your doctor where EPIDIOLEX can take you



Reduces seizures associated with LGS, Dravet syndrome, or TSC—even among those for whom multiple previous seizure medicines did not work well.



Safety evaluated across 4 studies involving more than 700 people.



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



The EPIDIOLEX®
Copay Savings
Program makes
it simple to
save. Ask
your specialty
pharmacy about
your eligibility.





For the latest updates, information, and stories about EPIDIOLEX, visit us on **Facebook** @**EPIDIOLEX** and subscribe at **youtube.com/EPIDIOLEX** 

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