

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 full Important Safety Information on pages 17-18 of this brochure and <u>click</u> <u>here for full Prescribing Information</u>.



# Families share everything.

For many, that includes the fears and frustrations of living with seizures. But with seizure reduction from EPIDIOLEX, families like yours can share something else. They can experience more moments of hope, like Ellamee's family, and look forward to what comes next with fewer seizures.



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- · 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





### 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 antiseizure medicines (ASMs).



Can be used to treat those 1 year of age or older.



Safety evaluated across 4 studies involving more than 700 people.



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



More than [50,000] families 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 altogether. As of 2023, EPIDIOLEX had the largest clinical study program across these conditions to date.

Even after these studies were completed, up to 99% of people went on to participate in 3-year open-label studies. Many continued to have fewer seizures.



#### 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 for your family.

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

Like other antiseizure medicines, EPIDIOLEX may cause suicidal thoughts or actions in a very small number of people, about 1 in 500. Call your doctor 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 LGS

# EPIDIOLEX significantly reduced drop seizures in people living with LGS

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



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 among those taking placebo.

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

Take EPIDIOLEX exactly as your doctor tells you. Do not stop taking EPIDIOLEX without first talking to your doctor. Stopping an antiseizure medicine suddenly can cause serious problems.



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



#### 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
- 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\*

75% OR GREATER

reduction in drop seizures was seen in 3x more people living with LGS on EPIDIOLEX 10 mg/kg/day (11%), compared with placebo (3%).

In the study, the most common ASMs taken were clobazam, valproate, lamotrigine, and levetiracetam.

#### **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.



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

#### 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.



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

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

#### **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 doctor. Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, herbal supplements, and cannabis-based products.



<sup>\*</sup>Convulsive seizures included tonic, tonic-clonic, atonic, and clonic.

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



75% OR GREATER

**reduction** in convulsive seizures was seen in nearly **2x more people** living with Dravet syndrome on 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.

In the study, the most common ASMs taken were clobazam, valproate, and stiripentol.

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

If you are pregnant or plan to become pregnant, EPIDIOLEX may harm your unborn baby, and medicines like EPIDIOLEX may be passed into breast milk. You and your doctor will decide if you should take EPIDIOLEX and about the best way to feed your baby while taking EPIDIOLEX.



#### 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.



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

6% of people taking EPIDIOLEX achieved freedom from TSC-associated seizures (compared with 0% of people taking placebo).

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

If you become pregnant while taking EPIDIOLEX, discuss registering with the EPIDIOLEX Pregnancy Surveillance Program (855-272-7158 or epidiolexpregnancystudy.com) and the North American Antiepileptic Drug Pregnancy Registry (888-233-2334 or aedpregnancyregistry.org). The purpose of these registries is to collect information about the safety of antiseizure medicines during pregnancy.



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



75% OR GREATER

**reduction** in TSC seizures was seen in more people with TSC on EPIDIOLEX 25 mg/kg/day (19%), compared with 0% of people taking placebo.

In the study, the most common ASMs taken were valproate, vigabatrin, levetiracetam, and clobazam.

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

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# Key things to know about EPIDIOLEX



# What is the most important information I should know about EPIDIOLEX?

EPIDIOLEX may cause liver problems. Your doctor may order blood tests to check your liver before and during EPIDIOLEX 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 antiseizure medicines, EPIDIOLEX may cause suicidal thoughts or actions in a very small number of people, about 1 in 500. Call your doctor 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. To watch for early symptoms of suicidal thoughts and actions, pay attention to any changes, especially sudden changes in mood, behaviors, thoughts, or feelings. Keep all follow-up visits with your doctor as scheduled.

Do not stop taking EPIDIOLEX without first talking to your doctor. Stopping a seizure medicine such as EPIDIOLEX suddenly can cause you to have seizures more often or seizures that do not stop (status epilepticus).

Call your doctor between visits as needed, especially if you are worried about symptoms.





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

EPIDIOLEX may interact with some antiseizure 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
- Across studies in LGS, Dravet syndrome, and TSC, EPIDIOLEX was found to have a consistent safety profile in both children and adults
- 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
- EPIDIOLEX can cause weight loss
- Your doctor may also order blood tests to look out for other side effects
- These are not all of the possible EPIDIOLEX side effects. For more information, ask your doctor or pharmacist



# Experience the EPIDIOLEX difference



#### **Naturally grown**

The active ingredient in EPIDIOLEX is not synthetic. It is a highly purified form of CBD medicine that is greenhouse-grown from non-GMO plants.

EPIDIOLEX is contaminant free. Strict regulations make sure EPIDIOLEX contains no toxic heavy metals, no pesticides, and no contaminants.



#### 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 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 delivery of quality that meets FDA standards.

<sup>&</sup>lt;sup>†</sup>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.



<sup>\*</sup>Source: https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products





The active ingredient in EPIDIOLEX is cannabidiol (CBD). Other ingredients that make up EPIDIOLEX include dehydrated alcohol, sesame seed oil, strawberry flavor, and sucralose (an artificial sweetener). Both strawberry flavor and sucralose are compatible with 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. Food may affect EPIDIOLEX levels, so be sure to take EPIDIOLEX consistently with or without food.

If necessary, EPIDIOLEX can be administered with certain nasogastric tubes (NG-tube) or gastrostomy tubes (G-tube). There are important considerations that you need to be aware of when administering EPIDIOLEX using feeding tubes. For specific instructions, please see the EPIDIOLEX Prescribing Information and talk to your doctor for more information.

#### 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.

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# The EPIDIOLEX® Copay Savings Program

#### Savings made simple

The copay savings program is designed to help make EPIDIOLEX affordable and accessible for eligible commercially insured patients.\*



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. Other restrictions, including monthly and/or annual maximum limits, may apply.

We know insurance coverage may seem complex, but the EPIDIOLEX support program is here to help. For more information about paying for your medicine, call 1-833-426-4243. Customer service associates are available Monday through Friday, 8:00 AM-8:00 PM ET (excluding holidays).



To learn more about a comprehensive support program that helps with access and affordability for patients taking EPIDIOLEX, including the EPIDIOLEX® Copay Savings Program, go to JazzCares.com/patients/epidiolex



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

# EPIDIOLEX supports you every step of the way

When you sign up for the EPIDIOLEX support program, you'll receive practical tools, tips, and information.

#### Stay up to date with the latest from EPIDIOLEX

We'll send you helpful information about the medicine, CBD, FDA approval, and a doctor discussion guide.

#### Stay on track

Get personalized support every step of the way, along with resources and tools to help with your treatment goals.

#### Hear from fellow caregivers

Receive tips and guidance from our community.

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





EPIDIOLEX ships directly to your home for free.





#### **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 doctor tells you. Do not stop taking EPIDIOLEX without first talking to your doctor. Stopping an antiseizure 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 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 Additional Information Applies to Women?**

If you are pregnant or plan to become pregnant, EPIDIOLEX may harm your unborn baby, and medicines like EPIDIOLEX may be passed into breast milk. You and your doctor will decide if you should take EPIDIOLEX and about the best way to feed your baby while taking EPIDIOLEX. If you become pregnant while taking EPIDIOLEX, discuss registering with the EPIDIOLEX Pregnancy Surveillance Program (855-272-7158 or <a href="mailto:epidiolexpregnancystudy.com">epidiolexpregnancystudy.com</a>) and the North American Antiepileptic Drug Pregnancy Registry (888-233-2334 or <a href="mailto:aedpregnancyregistry.org">aedpregnancyregistry.org</a>). The purpose of these registries is to collect information about the safety of antiseizure medicines during pregnancy.

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Please read 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 <a href="www.fda.gov/medwatch">www.fda.gov/medwatch</a> or call 1-800-FDA-1088. You may also contact Jazz Pharmaceuticals at 1-800-520-5568.



Every day we're surprised by Cameron and his potential. It just gives me such joy now."

-Jon, Cameron's dad

See what fewer seizures can mean for your family.

Talk to your doctor about EPIDIOLEX today.

Visit <u>EPIDIOLEX.com/patient-stories</u> for more stories of hope and resilience.





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

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