

YOUR EASY GUIDE TO EPIDIOLEX

Everything you need to know to get started




 **Epidiolex**[®]
(cannabidiol) 

Please see Important Safety Information on pages 18 and 19 of this booklet.
Please refer to the Prescribing Information, including the Medication Guide and Instructions for Use, on EPIDIOLEX.com



Getting started

So, your doctor has prescribed EPIDIOLEX® (cannabidiol) —an FDA-approved, purified form of cannabidiol made from plants. What comes next? This booklet will help you get started and know what to expect at every step.

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- Getting support 12-13
- Answers to common questions..... 14-17
- Important Safety Information 18-19

Use the space below to keep important contact information for doctors and specialty pharmacies in one place:

If you have questions about your medicine, call Greenwich Biosciences at 1-833-424-6724 (1-833-GBIOSCI) or visit EPIDIOLEX.com.

For questions about the ENGAGE support services, please 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).

From Prescription to Your Doorstep: What Happens In Between



Now that you've been prescribed EPIDIOLEX, you're probably eager to get started. Here's what comes next.

- 1** Your doctor and staff will submit your prescription. It will be sent to the specialty pharmacy that works with your insurance to determine coverage.
- 2** **You will probably receive a call from the pharmacy (look out for a 1-800 number)** or your healthcare provider to get any information needed to finish filling your prescription.
- 3** Once your insurance has been approved, the medicine will be shipped directly to your house. There is no shipping cost involved. The aim is to get your prescription filled as quickly as possible, but this may take some time.



Did you know? Specialty pharmacies have expertise in preparing and filling medicines like EPIDIOLEX. They fill FDA-approved prescriptions just as traditional pharmacies do.

Certain specialty pharmacies can ship your medicine to a local store for pickup. If you are interested in this option, talk to your specialty pharmacy to find out more.

 **Epidiolex**[®]
(cannabidiol) 

Your EPIDIOLEX has arrived

See What's Inside

Now that your shipment has been delivered, you should check to make sure it contains everything listed below.

1 Medication Box

- 1 or more (depending on your prescription) bottles of EPIDIOLEX with child-resistant cap
- Bottle adapter
- 2 reusable 5 mL or 1 mL oral syringes
 - 1 syringe to take or give the dose of EPIDIOLEX
 - 1 extra syringe (so you always have a dry one)

Since the dose is prepared specifically for you, it's possible that you will receive multiple bottles of EPIDIOLEX and/or a partially filled bottle that will have a label from the specialty pharmacy. It may look a little different, but the medicine is exactly the same.



Taking EPIDIOLEX for the first time

Taking EPIDIOLEX can be easy if you follow a few simple instructions. Visit the links below to watch an experienced caregiver give EPIDIOLEX to his son, or follow the directions on the next pages. Make sure to use the dosing schedule provided by your doctor (see page 10 for more information on dosing, including a helpful worksheet).



**Setting up and preparing
to administer EPIDIOLEX.**

EPIDIOLEX.com/Prep



**Step-by-step instructions
for taking EPIDIOLEX.**

EPIDIOLEX.com/Taking



**How to clean and store the
syringe and plunger after
each use.**

EPIDIOLEX.com/Clean



Scan this code with your
smartphone's camera to
watch these videos.



Taking EPIDIOLEX

Follow the simple instructions below.

Step 1: Putting on the Bottle Adapter

- 1 Remove bottle cap.
- 2 Push the bottle adapter firmly into the bottle. **Do not** remove the adapter after it has been inserted.

Tip: if you have trouble getting the bottle adapter on, insert the syringe into the bottle adapter and use that to help fit it into the bottle.



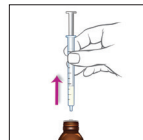
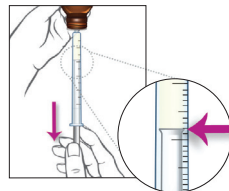
Because syringes can differ, these instructions may not apply if you buy your own.

Step 2: How to Prepare the Right Dose

- 1 Push the plunger all the way down and insert the tip of the syringe into the bottle adapter. Turn the bottle upside down.
- 2 Slowly pull the plunger to withdraw the dose.
- 3 Line up the end of the plunger with the marking for your dose.

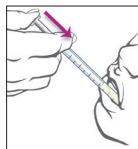
Tip: If you see air bubbles, flick the syringe while the bottle is still upside down to get the air bubbles to the top then push it back into the bottle. Repeat the process until the air bubbles are gone.

- 4 Leave the syringe in and turn the bottle right-side up.
- 5 Carefully remove the syringe.



Step 3: How to Give EPIDIOLEX

- 1 Place the tip of the syringe against the inside of the cheek and gently push the plunger until all the EPIDIOLEX is given.



- o **Do not** force the plunger down.
- o **Do not** direct the medicine to the back of the mouth or throat. This may cause choking.



Dosing Tips: If the dose is more than 5 mL, you'll need to fill the syringe twice. For example, for an 8 mL dose, first withdraw 5 mL, administer it, and then withdraw another 3 mL.

If the prescribed dose is not a whole number, let's say 3.8 mL, here's what you do: draw past the 3 mL line until you reach 3.8 mL.

If you were sent 1 mL syringes, you can prepare a dose the same way. For example, if the dose is 0.35 mL, you will draw up to the 0.3 mL line, and then go 1 hashmark further to 0.35 mL. If the prescribed dose is between hashmarks, ask your doctor for instructions on rounding.

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

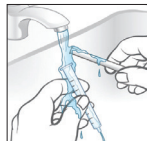
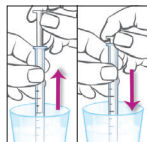
 **Epidiolex**[®]
(cannabidiol) 



Taking EPIDIOLEX (cont'd)

Step 4: Cleaning Up

- 1** Screw the child-resistant cap tightly back on the bottle. There is no need to remove the adapter, as the cap will fit over it.
- 2** Fill a cup with warm soapy water and clean the syringe by drawing water in and out of the syringe, using the plunger.
- 3** Remove the plunger from the barrel of the syringe and rinse both parts under tap water. Never use the dishwasher.
- 4** Shake off the plunger and syringe and allow them to air dry completely until the next use.



Here are a few things to keep in mind as you start treatment:

- EPIDIOLEX is an oral solution that is taken twice daily. It should be taken consistently with respect to meals.
- EPIDIOLEX was made without sugar or carbohydrates to work with most epilepsy diets, such as the ketogenic diet. However, always talk to your doctor about your dietary therapy or any changes to dietary therapy before taking.
- After each use, be sure to wash the syringes and let them dry completely. If they're not totally dry, water could mix in with the medicine and cause it to look cloudy. This doesn't mean the medicine has gone bad.
- If the oral syringe is not completely dry, use the spare syringe provided to you. If you need a reminder on how to hand wash your syringe, refer to the "Cleaning Up" section.
- 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.

If you still have questions, talk to your doctor or visit **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 Dosing Explained

When starting EPIDIOLEX, your doctor may begin with a lower dose and slowly increase the amount of medicine to reach the dose he/she believes is right for you.

Once that dose is reached, your doctor will evaluate your response.

If needed, your doctor may adjust your dose further.



Remember:

- EPIDIOLEX is an oral solution that is taken twice daily. It should be administered consistently with respect to meals.
- You should take EPIDIOLEX exactly as your doctor tells you. Do not stop taking EPIDIOLEX without first talking to your doctor. Stopping a seizure medicine suddenly can cause serious problems.
- When the dose of EPIDIOLEX was increased to 20 mg/kg/day from the maintenance dose of 10 mg/kg/day, there was a somewhat greater reduction in seizure rates; however, there was also an increase in side effects.
- Be sure to tell your doctor if you are taking any other medicines so he or she can take that into account when creating your dosing schedule.
- Your doctor may also request blood work to evaluate liver function before you start and during treatment.

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.





Join Our Family of Caregivers

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™* 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 epidioxontheego.com](https://www.epidioxontheego.com)

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

COPAY

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. For eligible patients only. Eligibility assessed on an individual basis.



We know insurance coverage may seem complex, but the *EPIDIOLEX ENGAGE*™ 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).

*For Terms and Conditions, please visit [EPIDIOLEX.com/Terms-Conditions](https://www.epidiolex.com/terms-conditions).



		DOSE (mL)		DAY 1 Date													
Week 1	AM DOSE (mL)	_____ mL		1		2		3		4		5		6		7	
	PM DOSE (mL)	_____ mL															
Week 2	AM DOSE (mL)	_____ mL		8		9		10		11		12		13		14	
	PM DOSE (mL)	_____ mL															
Week 3	AM DOSE (mL)	_____ mL		15		16		17		18		19		20		21	
	PM DOSE (mL)	_____ mL															
Week 4	AM DOSE (mL)	_____ mL		22		23		24		25		26		27		28	
	PM DOSE (mL)	_____ mL															

Please see Important Safety Information on pages 18 and 19 of this booklet.

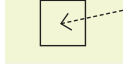

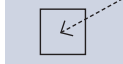



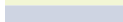

Please refer to the Prescribing Information, including the Medication Guide and Instructions for Use, on EPIDIOLEX.com

Dosing Worksheet

Use the worksheet on the opposite side to keep track as you start EPIDIOLEX and work toward the dose that's right for you.

Week 1	 AM DOSE (mL)	DOSE (mL) _____ mL
	 PM DOSE (mL)	_____ mL

YOUR DOCTOR will fill in the dose he or she would like you to take on Week 1. If your dose is to be adjusted over the following weeks, your doctor will enter revised doses in the subsequent rows.

1		2	
			
8		9	
			

YOU will track dose administration as noted by your doctor. Check the box for each morning and evening dose.

Please see Important Safety Information on pages 18 and 19 of this booklet.

Please refer to the Prescribing Information, including the Medication Guide and Instructions for Use, on [EPIDIOLEX.com](https://www.epidiox.com)

For more information about dosing and additional worksheets, visit [EPIDIOLEX.com/dosing](https://www.epidiox.com/dosing)



Please see Important Safety Information on pages 18 and 19 of this booklet.

Please refer to the Prescribing Information, including the Medication Guide and Instructions for Use, on [EPIDIOLEX.com](https://www.epidiox.com)

① Answers to Common Questions

What is EPIDIOLEX (cannabidiol)?

EPIDIOLEX is an FDA-approved medicine containing purified cannabidiol made from plants that is used to treat seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome in patients 2 years of age or older.

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 the first 4 weeks of treatment, while most improved throughout the 14-week study.

Adverse reactions were similar across LGS and Dravet in pediatric and adult patients.

In controlled studies, the rates of discontinuation (patients who stopped taking the medicine) for any adverse event

were: 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.

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

These are not all the possible side effects of EPIDIOLEX. For more information, ask your healthcare provider or pharmacist.

What if there are air bubbles in the oral syringe?

If there are air bubbles in the oral syringe, keep the bottle upside down and push the plunger so that all of the liquid flows back into the bottle. Slowly pull the plunger of the oral syringe to withdraw the dose of EPIDIOLEX. You can

also flick the syringe to get the air bubbles to the top, then push it back into the bottle. Repeat the process until the air bubbles are gone.

What should I do if the oral syringe is not completely dry before use?

If the oral syringe is not completely dry, use the spare syringe provided to you. If water is inside the syringe, it could cause the oil-based medicine to look cloudy and may mean you receive less EPIDIOLEX than usual.

What should I do if the liquid in the bottle has turned cloudy?

If the syringes are not totally dry, water could mix in with the medicine and cause it to look cloudy. But don't worry, the cloudiness doesn't affect how well the medicine works.

If you have questions about your medicine, call your doctor. You may also contact Greenwich Biosciences at 1-833-424-6724 (1-833-GBIOSCI).

Can EPIDIOLEX result in a positive drug test?

Tell your healthcare provider if you are planning to have a cannabis drug screening, because EPIDIOLEX may affect your test results. Tell the person giving the drug test that you are taking EPIDIOLEX, a medicine prescribed by your doctor. It may even be helpful to bring your prescription with you if any questions come up.

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.



Answers to Common Questions (cont'd)

What do I do if I break or lose my syringes or medication bottle?

If your bottle of EPIDIOLEX happens to break, call your specialty pharmacy as soon as possible to learn about your options.

How should I store EPIDIOLEX, and does it expire?

Keep the bottle upright and use within 12 weeks after first opening, throwing away any unused medicine after that. An unopened bottle of EPIDIOLEX has an expiration date of 24 months. Store at room temperature between 68°F to 77°F (20°C to 25°C) and never freeze it. Keep the child-resistant cap tightly closed, and always keep out of reach of children.

Does EPIDIOLEX interact with my other medications?

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.

Is EPIDIOLEX compatible with a ketogenic diet?

EPIDIOLEX was made without sugar or carbohydrates to be compatible with most epilepsy diets, such as the ketogenic diet. However, always talk to your doctor about your dietary therapy or any changes to dietary therapy before taking EPIDIOLEX.

Does EPIDIOLEX contain dairy, gluten, or nuts?

Dairy products are not used in the manufacturing of EPIDIOLEX. EPIDIOLEX does not contain gluten (wheat, barley, or rye).

EPIDIOLEX is an oral solution of cannabidiol (100 mg/mL) in sesame seed oil. It is important to note that sesame is a seed, not a nut, so if you're allergic to one, you may not be allergic to the other. Sesame seed allergies have been estimated to affect 0.1% of the general population in the US. Nut allergies are more common and may affect 1.4% of the population. EPIDIOLEX should be avoided in patients with a known or suspected sesame seed allergy.

Will EPIDIOLEX get me/my loved one high?

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.

Is EPIDIOLEX legal?

EPIDIOLEX is an FDA-approved prescription and is therefore legal under federal law. Keep your prescription inside your travel case so it's always nearby should anyone need to see it.

If you have a question that's not listed here, visit [EPIDIOLEX.com/FAQs](https://www.epidiox.com/FAQs) where you can find the full list of FAQs.

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.



Indications & Important Safety Information

What is EPIDIOLEX?

EPIDIOLEX is a prescription medicine that is used to treat seizures associated with Lennox-Gastaut syndrome or Dravet syndrome 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.

Indications & Important Safety Information (cont'd)

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.

You may also contact Greenwich Biosciences at 1-833-424-6724 (1-833-GBIOSCI).

Your Journey Has Just Begun

Even though you've reached the end of this booklet, your treatment journey is just beginning. We'll be here to support you throughout. Keep this guide as a resource to come back to.

For any special notes/instructions:

If you have questions about your medicine, call Greenwich Biosciences at 1-833-424-6724 (1-833-GBIOSCI) or visit [EPIDIOLEX.com](https://www.epidiolex.com)

We aim to be available to support you on this journey. For questions about the ENGAGE support services, please 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).



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