



Your easy guide to EPIDIOLEX

Everything you need to know to get started

 **Epidiolex**[®]
(cannabidiol)

Please see full Important Safety Information on pages 20 and 21
of this booklet and click here for full [Prescribing Information](#).

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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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](https://www.epidiox.com)

For questions about EPIDIOLEX 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 coverage is 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.



Fill it fast: Most people receive their first bottle of EPIDIOLEX less than 12 days after their doctor prescribes it.

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 supports you every step of the way

Living with a serious and rare condition like Lennox-Gastaut syndrome (LGS), Dravet syndrome, or tuberous sclerosis complex (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. Your travel case includes space for your medication bottle and 2 syringes. Use the sleeve to keep your prescription slip and any seizure care instructions handy.



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**](https://www.epidiox.com/support)

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.

Select Important Safety Information

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



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 June 30, 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](https://www.epidiox.com/copay) for full terms and conditions, along with the latest program info.

[†]On July 1, 2021, 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.

5 Please see full Important Safety Information on pages 20 and 21 of this booklet and click here for full [Prescribing Information](#).



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**[®]
(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.

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 pages 8-10. Make sure to use the dosing schedule provided by your doctor (see pages 12-15 for more information on dosing, including a helpful worksheet).



**Setting up and preparing
to administer EPIDIOLEX.**
[EPIDIOLEX.com/prep](https://www.epidiolex.com/prep)



**Step-by-step instructions
for taking EPIDIOLEX.**
[EPIDIOLEX.com/taking](https://www.epidiolex.com/taking)



**How to clean and store the
syringe and plunger after each
use.** [EPIDIOLEX.com/clean](https://www.epidiolex.com/clean)

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.

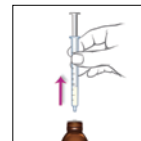
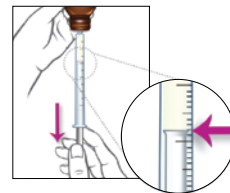
Tip: If you have trouble getting the bottle adapter on, insert the syringe into the bottle adapter and use that to help fit it into the bottle.



If you need a replacement, visit
[EPIDIOLEX.com/syringe](https://www.epidiox.com/syringe)

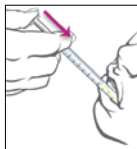
Step 2: How to Prepare the Right Dose

- 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.

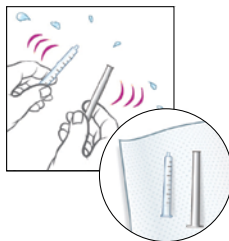
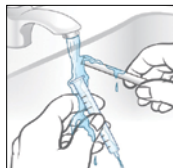
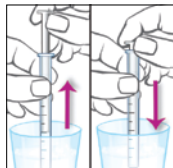
Select Important Safety Information

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

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
- 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)
- 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. To request additional syringes at no cost, visit [EPIDIOLEX.com/syringe](https://www.epidiolex.com/syringe)

If you still have questions, talk to your doctor or visit [EPIDIOLEX.com](https://www.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
- Your doctor may adjust your dose based on your response to EPIDIOLEX and whether you are experiencing 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 EPIDIOLEX 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.









Dosing worksheet

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

		DOSE (mL)
Week 1	 AM DOSE (mL)	<u> </u> mL
	 PM DOSE (mL)	<u> </u> 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.

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

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.

		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								



Answers to common questions

What is EPIDIOLEX?

EPIDIOLEX is the first and only FDA-approved prescription CBD to treat seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex in patients 1 year of age and older.

What are the possible side effects of 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.

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 rates of discontinuation (patients who stopped taking the medicine) for any side effect 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 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 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.

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. To request additional syringes at no cost, visit [EPIDIOLEX.com/syringe](https://www.epidiox.com/syringe)

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 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 have a flavor?

EPIDIOLEX contains an artificial sweetener called sucralose, as well as strawberry flavor for taste. Both are compatible with the ketogenic diet. However, if you are allergic to cannabidiol (CBD) or any of the ingredients in EPIDIOLEX, you should not take it.

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.

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

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.

Important Safety Information & Indications

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

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
- 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 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 increase in liver enzymes, sleepiness, decreased appetite, diarrhea, fever, vomiting, feeling very tired and weak, rash, sleep problems, and infections.

Important Safety Information & Indications (cont'd)

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.

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.

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It is not known if EPIDIOLEX is safe and effective in children under 1 year of age.

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).



See where EPIDIOLEX can take you

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 EPIDIOLEX 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).



For the latest updates, information, and stories about EPIDIOLEX, visit us on **Facebook @EPIDIOLEX** and subscribe at [youtube.com/EPIDIOLEX](https://www.youtube.com/EPIDIOLEX)

 **Epidiolex**[®]
(cannabidiol)



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