



Your easy guide to EPIDIOLEX

Everything you need to know to get started

Getting started

So your doctor has prescribed EPIDIOLEX® (cannabidiol)—an FDA-approved, purified form of cannabidiol (CBD) 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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Please see full Important Safety Information on pages 20 and 21 of this booklet and click here for full <u>Prescribing Information</u>.

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 Jazz Pharmaceuticals at 1-800-520-5568 or visit EPIDIOLEX.com
- If you have questions about EPIDIOLEX support services, please call 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.



Your doctor and staff will submit your prescription. It will be sent to the specialty pharmacy that works with your insurance to confirm coverage.



Fill it fast: Most people receive their first bottle of EPIDIOLEX less than 9 days after their doctor prescribes it.



Free shipping directly to your home.

2 You will probably get a call from the pharmacy (look out for a 1-800 number or local number).

You may not recognize the phone number, but it's important to answer the phone when the pharmacy calls to avoid delays with your EPIDIOLEX shipment.

Be sure to have your insurance and prescription information handy when the pharmacy calls.

You can also talk to your specialty pharmacy about the best way to communicate (phone, email, or text). Once your insurance coverage is confirmed, the prescription will be filled and the medicine will be shipped directly to your house. The aim is to get your prescription filled and delivered to you as quickly as possible, but this may take some time.

3

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.



\odot 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.



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.

EPIDIOLEX should be stored in an upright position. The EPIDIOLEX travel case is designed to keep your medicine and syringes safe and secure during travel. It is not designed for long-term storage.



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



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.*



As low as \$0 per prescription

The program is only for commercially insured patients prescribed EPIDIOLEX 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.

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

Please see full Important Safety Information on pages 20 and 21 of this booklet and click here for full <u>Prescribing Information</u>.

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/





See what's inside

Once your shipment has been delivered, 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 1 mL oral syringes and 2 reusable 5 mL oral syringes: If your dose of EPIDIOLEX is 1 mL or less, use the 1 mL syringes to take your medicine

For each syringe size:

- 1 syringe to take or give the dose of EPIDIOLEX
- 1 extra syringe (included as a spare if needed)

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

Follow the directions on pages 8-10 to learn how to properly administer EPIDIOLEX, or visit the links below to watch Jon, an experienced caregiver, give EPIDIOLEX to his son, Cameron. Make sure to use the dosing schedule provided by your doctor (see pages 12-13 for more information on dosing, including a helpful worksheet).





Setting up and preparing to administer EPIDIOLEX: **EPIDIOLEX.com/prep**









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.

These videos are also available in Spanish at EPIDIOLEX.com/videos-es





Taking EPIDIOLEX

Step 1: Putting on the bottle adapter

- 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 replacement syringes or adapters, visit **EPIDIOLEX.com/syringe**

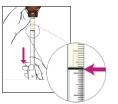




Step 2: How to prepare the right dose

- Push the plunger all the way down and insert the tip of the syringe into the bottle adapter. With the oral syringe in place, 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.
- Leave the syringe in and turn the bottle right-side up.
- **5** Carefully remove the syringe.











Taking EPIDIOLEX (cont'd)

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.
 - **Do not** force the plunger down
 - 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 hash mark further to 0.35 mL. If the prescribed dose is between hash marks, ask your doctor for instructions on rounding.

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.







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 with certain nasogastric tubes (NG-tube) or gastrostomy tubes (G-tube). For specific instructions, please see the EPIDIOLEX Prescribing Information and talk to your doctor for more information
- EPIDIOLEX was made without sugar 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 <u>EPIDIOLEX.com/syringe</u>

If you still have questions, talk to your doctor or visit <u>EPIDIOLEX.com</u>

Select Important Safety Information

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 dosing explained

When starting EPIDIOLEX, your doctor may begin with a lower dose and slowly increase the amount of medicine to reach the dose they believe is right.

Once that dose is reached, your doctor will evaluate your/your loved one's response.

Weight can impact dosing, so your doctor may adjust your dose further if needed and titration may be required to achieve the optimal dose.





EPIDIOLEX dosing explained (cont'd)

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 an antiseizure 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 they 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

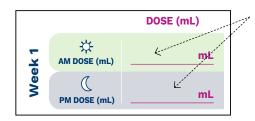
EPIDIOLEX may cause you to feel sleepy, which may get better over time. Other medicines (e.g., clobazam) or alcohol may increase sleepiness. Do not drive, operate heavy machinery, or do other dangerous activities until you know how EPIDIOLEX affects you.



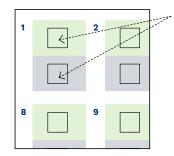


Dosing worksheet

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



YOUR DOCTOR will fill in the dose they 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.



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





* Epidiolex® (cannabidiol)

Answers to common questions

What is **EPIDIOLEX**?

EPIDIOLEX is the first and only FDA-approved prescription cannabidiol (CBD) to treat seizures associated with Lennox-Gastaut syndrome (LGS), Dravet syndrome, or tuberous sclerosis complex (TSC) 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.

Please see full Important Safety Information on pages 20 and 21 of this booklet and click here for full **Prescribing Information**.

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 doctor or pharmacist.



Answers to common questions (cont'd)

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.

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. The most common medicines taken during clinical trials were clobazam, valproate, lamotrigine, and levetiracetam.

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. Repeat the process until the air bubbles are gone.

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.



Answers to common questions (cont'd)

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.

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 Jazz Pharmaceuticals at 1-800-520-5568.

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**

Can EPIDIOLEX be taken with a feeding tube?

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 healthcare provider for more information.



Answers to common questions (cont'd)

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. Do not use EPIDIOLEX after the expiration date on the package and each bottle. Store at room temperature between 68°F to 77°F (20°C to 25°C) and never freeze it. Keep the childresistant cap tightly closed, and always keep out of reach of children.

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 CBD or any of the ingredients in EPIDIOLEX, you should not take it.

Does EPIDIOLEX contain dairy, gluten, or nuts?

EPIDIOLEX does not contain dairy products or gluten (wheat, barely, 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. While a nut allergy does not necessarily mean you're allergic to seeds, there may still be sensitivity to sesame. EPIDIOLEX should be avoided in patients with a known or suspected sesame seed allergy. Talk to your doctor if you have any more questions about allergies or dietary restrictions that may impact you or your loved one.

If you have a question that's not listed here, visit <u>EPIDIOLEX.com/FAQs</u> where you can find the full list of FAQs.



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 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.

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.



Important Safety Information & Indications (cont'd)

What Else Should I Know When Taking EPIDIOLEX?

The most common side effects of EPIDIOI FX 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 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.

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 read 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 Jazz Pharmaceuticals at 1-800-520-5568.



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 Jazz Pharmaceuticals at 1-800-520-5568 or visit <u>EPIDIOLEX.com</u>

We aim to be available to support you on this journey. For questions about EPIDIOLEX support services, please call 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**



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