

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrEPIDIOLEX®

#### Cannabidiol oral solution

Read this carefully before you start taking **EPIDIOLEX** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **EPIDIOLEX**.

#### What is EPIDIOLEX used for?

EPIDIOLEX is used in combination with other medicines used to treat seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex in patients 2 years of age and older.

#### How does EPIDIOLEX work?

The way that EPIDIOLEX works is not fully understood. However, it is thought that EPIDIOLEX works by lowering the excitability of the brain cells that cause seizures.

#### What are the ingredients in EPIDIOLEX?

Medicinal ingredient: cannabidiol

Non-medicinal ingredients: anhydrous alcohol, sesame seed oil, strawberry flavouring, and sucralose

#### EPIDIOLEX comes in the following dosage forms:

Oral solution: 100 mg/mL

#### Do not use EPIDIOLEX if:

- you are allergic to EPIDIOLEX or any of its ingredients.
- if your healthcare professional determines that you have certain abnormal liver blood tests.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take EPIDIOLEX. Talk about any health conditions or problems you may have, including if you:**

- have liver problems.
- have or had depression or have tried to harm yourself.
- are pregnant, think you are pregnant, or plan to become pregnant.
- are breastfeeding or plan to breastfeed. It is not known if EPIDIOLEX passes into your breast milk.

#### Other warnings you should know about:

**Pregnancy:** EPIDIOLEX may harm your unborn baby. Only take EPIDIOLEX during pregnancy if you and your healthcare professional have discussed the risks and have decided that you should. If you become pregnant while taking EPIDIOLEX, talk to your healthcare professional about registering with the North American Antiepileptic Drug Pregnancy Registry. You can enroll in this registry by calling 1-888-233-2334. The purpose of this registry is to collect information about the safety of antiepileptic medicines

during pregnancy. Information on the registry can also be found at the following website:

<https://www.aedpregnancyregistry.org/>.

**Fertility:** If you are a woman of child-bearing potential or a fertile man, use reliable contraception during your treatment with EPIDIOLEX.

**Driving and using machines:** EPIDIOLEX can make you feel sleepy. Avoid driving and using machinery until you know how EPIDIOLEX affects you.

**Monitoring and Tests:** Your healthcare professional may perform tests before you start treatment with EPIDIOLEX and while you are taking it. Your healthcare professional may monitor:

- your liver function and enzyme levels.
- your mood and behaviour.

**Tell your healthcare professional if you are planning to have a cannabis drug test.** EPIDIOLEX may affect your test results. Tell the person giving the drug test that you are taking EPIDIOLEX.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with EPIDIOLEX:**

- Alcohol may increase sleepiness.
- Caffeine may increase the effects of EPIDIOLEX.
- Other medicines used to treat seizures, such as carbamazepine, clobazam, lamotrigine, lorazepam, phenytoin, stiripentol and valproate.
- Medicines used to treat bacterial infections, such as rifampin, clarithromycin, and erythromycin.
- Other medicines used to treat tuberous sclerosis complex including everolimus.
- Medicines used to treat acid reflux (heartburn or acid regurgitation) such as omeprazole.
- Medicines used in the treatment of anxiety, such as diazepam and clobazam.
- St. John's wort (*Hypericum perforatum*) (a herbal medicine that may be used to treat mild depression or mild anxiety).

EPIDIOLEX may interact with many other medicines. If you are unsure about any of the medicines you take, talk to your healthcare professional.

**How to take EPIDIOLEX:**

- Read the “**Instructions for the Oral Use of EPIDIOLEX**” below for detailed instructions on how to use EPIDIOLEX.
- Take EPIDIOLEX exactly as your healthcare professional tells you to.
- EPIDIOLEX can be taken with or without food, but you should try to take it the same way each day (either with food, or without food), so you get the same effect each time.
  - If you take EPIDIOLEX with food, try to take it with a similar meal type each time (e.g., a meal with a similar fat content).
- Do NOT stop taking EPIDIOLEX suddenly, as this can increase the number of seizures you have and their severity. If you want to stop your treatment, talk to your healthcare professional first.
- If necessary, EPIDIOLEX may be taken via a nasogastric or gastrostomy tube. Your healthcare professional will give you directions on how to do this. Check with your healthcare professional if you are not sure.

**Usual dose:**

Your healthcare professional will tell you how much EPIDIOLEX to take each day, when to take it and which syringe you should use for your dose (1 mL or 5 mL).

The dose is calculated according to your body weight. You may start on a low dose that your healthcare professional gradually increases over time. If you have any questions about your dose, talk to your healthcare professional.

**Instructions for the Oral Use of EPIDIOLEX:****Important:**

- Follow your healthcare professional's instructions for the dose of EPIDIOLEX to take or give.
- Ask your healthcare professional if you are not sure how to prepare, take, or give the prescribed dose of EPIDIOLEX.
- Always use the oral syringe provided with EPIDIOLEX to make sure you measure the right amount of EPIDIOLEX.
- Do not use EPIDIOLEX after the expiration date on the package and each bottle.
- Use EPIDIOLEX within 12 weeks of first opening the bottle.
- After 12 weeks, safely dispose of any EPIDIOLEX that has not been used.

**Each package contains:**

Child-resistant cap



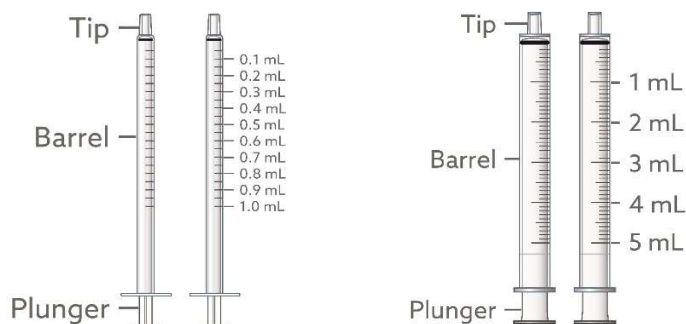
2 bottle adapters



1 bottle of EPIDIOLEX oral solution (100 mg/mL)



**2 reusable 1 mL oral syringes and 2 reusable 5 mL oral syringes:**



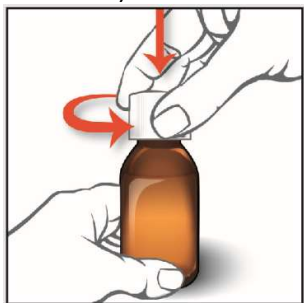
For each syringe size:

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

Note: If you lose or damage an oral syringe, or cannot read the markings, use the spare syringe.

**Prepare The Bottle - to use EPIDIOLEX for the first time**

1. Remove the child-resistant cap by pushing down while turning the cap to the left (counter-clockwise).



2. Push a bottle adapter firmly into the bottle.

**Make sure the bottle adapter is fully inserted.** If not fully inserted, small parts such as the bottle adapter may become a choking hazard for children and pets.

Note: **Do not** remove the bottle adapter from the bottle after it is inserted.



## Prepare The Dose

Your healthcare provider will tell you how much EPIDIOLEX to take or give.

3. Use this table to measure the total dose of EPIDIOLEX.

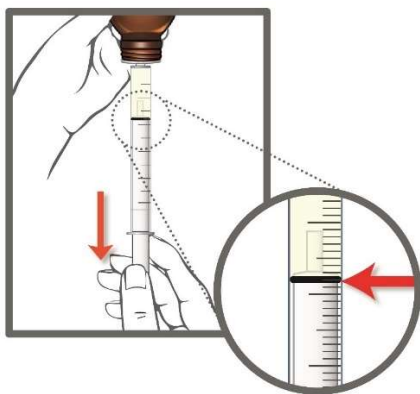
Dose	How to measure
1 mL or less	Use the 1 mL oral syringe <b>1 time</b>
More than 1 mL and less than 5 mL	Use the 5 mL oral syringe <b>1 time</b>
More than 5 mL	Use the 5 mL oral syringe more than 1 time

4. Push the plunger all the way down and insert the tip of the oral syringe fully into the bottle adapter. With the oral syringe in place, turn the bottle upside down.



5. Slowly pull the plunger of the oral syringe to withdraw the dose of EPIDIOLEX needed.

**Line up** the end of the plunger with the marking for your dose of EPIDIOLEX.



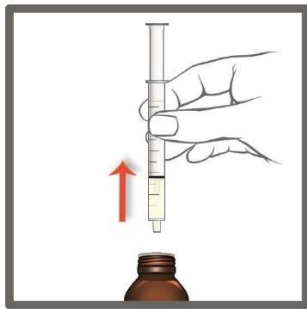
### What to do if you see air bubbles:

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. Repeat **Step 5** until the air bubbles are gone.

6. When you have measured the correct dose of EPIDIOLEX, leave the oral syringe in the bottle adapter and turn the bottle right side up.

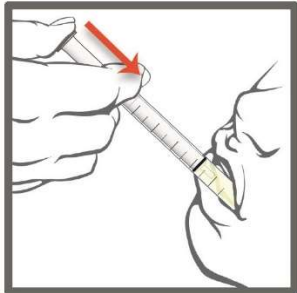


7. Carefully remove the oral syringe from the bottle adapter.



#### Give EPIDIOLEX

8. Place the tip of the oral syringe against the inside of the cheek and gently push the plunger until all the EPIDIOLEX in the syringe is given.



**Do not** forcefully push on the plunger.

**Do not** direct the medicine to the back of the mouth or throat. This may cause choking.

**If the dose of EPIDIOLEX prescribed by the healthcare provider is more than 5 mL, repeat steps 4 through 8 to complete the dose.**

For example:

If your dose of EPIDIOLEX is 8 mL, withdraw 5 mL of medicine into the syringe and give the medicine. Insert the tip of the oral syringe back into the bottle adapter and withdraw 3 mL of medicine. Give the medicine to receive a total dose of 8 mL.

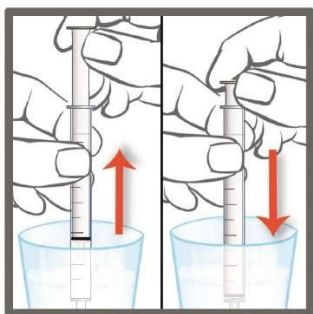
## Clean Up

9. Screw the child-resistant cap back on the bottle tightly by turning the cap to the right (clockwise).



**Do not** remove the bottle adapter. The cap will fit over it.

10. Fill a cup with warm soapy water and clean the oral syringe by drawing water in and out of the syringe using the plunger.

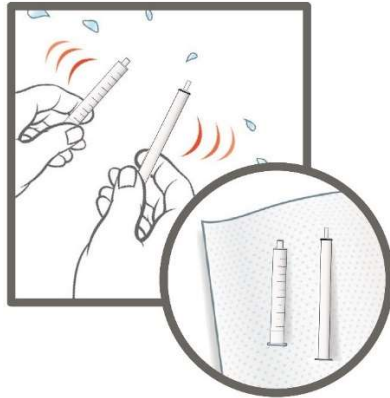


11. Remove the plunger from the barrel of the oral syringe and rinse both parts under tap water.



**Do not** wash the oral syringe in the dishwasher.

12. Shake off any extra water from the plunger and oral syringe barrel and **allow them to air dry until next use.**



**Make sure** the oral syringe is completely dry before the next use.

If water is inside the syringe, it could cause the oil-based medicine to look cloudy. This does not change the safety or how well the medicine works. Continue to use the cloudy liquid as prescribed by your healthcare provider.

If the oral syringe is not completely dry, use the spare syringe provided in the pack.

**Do not throw away the oral syringe.**

#### Overdose:

If you think you, or a person you are caring for, have taken too much EPIDIOLEX, contact a healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

#### Missed Dose:

If you forget to take a dose, do not take a double dose to make up for a forgotten dose. Skip the missed dose and take the next dose at your regular time. If you miss more than 7 days of doses, please talk to your healthcare professional about the correct dose to take.

#### What are possible side effects from using EPIDIOLEX?

These are not all the possible side effects you may have when taking EPIDIOLEX. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- diarrhea
- tiredness or loss of energy
- sleepiness or drowsiness
- decreased appetite
- feeling irritable
- fever
- vomiting
- nausea
- constipation
- cough
- rash
- change in walking or gait

It is **very common** for EPIDIOLEX to cause abnormal liver test results. Your healthcare professional will do blood tests during your treatment to monitor your liver enzyme levels. If you experience dark urine, fatigue, abdominal pain, loss of appetite, or yellowing of the skin or eyes, talk to a healthcare



professional **right away**.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Status epilepticus (a single long-lasting seizure or several shorter seizures that occur without consciousness between seizures)			√
COMMON			
Anemia (decreased number of red blood cells): fatigue, loss of energy, looking pale, shortness of breath, weakness		√	
Eosinophilia (increased number of certain white blood cells): abdominal pain, rash, weight loss, wheezing		√	
Pneumonia (infection in the lungs): chest pain when you breath or cough, confusion, cough which may produce phlegm, fatigue, fever, sweating and shaking chills, nausea, vomiting or diarrhea, shortness of breath		√	
Urinary tract infection (infection in urinary system): pain or burning sensation while urinating, frequent urination, blood in urine, pain in the pelvis, strong smelling urine, cloudy urine		√	
Weight loss	√		
NOT KNOWN			
Allergic reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			√
Thoughts of suicide or hurting yourself		√	
Worsening seizures: seizures happening more often in people who already have epilepsy		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### Storage:

Store EPIDIOLEX at room temperature (15°C to 30°C).

Always store EPIDIOLEX in an upright position. Protect from freezing.

Keep the child-resistant cap tightly closed.

Use EPIDIOLEX within 12 weeks of first opening the bottle. Dispose of any unused EPIDIOLEX after 12 weeks.

Keep out of reach and sight of children.

### If you want more information about EPIDIOLEX:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website [www.jazzpharma.com](http://www.jazzpharma.com); by calling 1-800-520-5568 or by email to [medinfo-ca@jazzpharma.com](mailto:medinfo-ca@jazzpharma.com).

This leaflet was prepared by Jazz Pharmaceuticals Research UK Limited

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Last Revised OCTOBER 30, 2024