

INSTRUCTIONS FOR USE

EPIDIOLEX[®]

(EH-peh-DYE-oh-lex)

(cannabidiol) oral solution
100 mg/mL

Be sure that you read, understand and follow these instructions carefully to ensure proper dosing of the oral solution.

Important:

- Follow your healthcare provider's instructions for the dose of EPIDIOLEX to take or give.
- Ask your healthcare provider or pharmacist 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 throw away (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

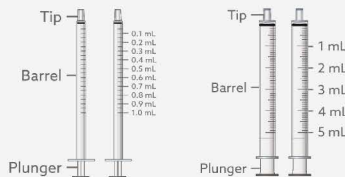
If your dose of EPIDIOLEX is 1 mL or less, use the 1 mL syringes to take your medicine.

For each syringe size:

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



Please note expiration date.



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 the 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 to be given.

Dose	How to measure
1 mL or less	Use the 1 mL oral syringe 1 time
More than 1 mL and less than 5 mL	Use the 5 mL oral syringe 1 time
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.

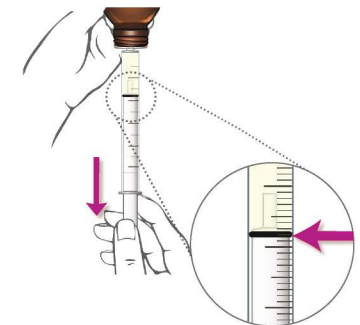


5 Slowly pull the plunger of the oral syringe to withdraw the dose of EPIDIOLEX needed. See **Step 3** for how to measure the total dose of EPIDIOLEX.

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

What to do if you see air bubbles:

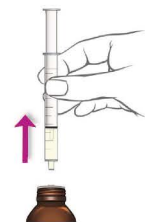
If there are air bubbles in the oral syringe, keep the bottle upside down and push the plunger so that all of the liquid flows back into the bottle. Repeat **Step 5** until the air bubbles are gone.



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.

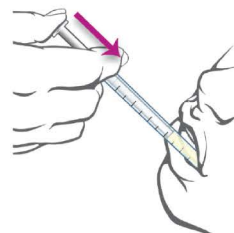
Do not forcefully push on the plunger.

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.



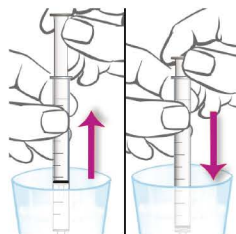
Clean Up

- 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.

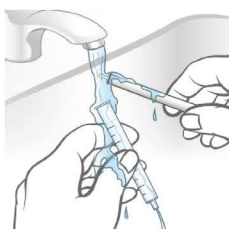


- 10** Fill a cup with warm soapy water and clean the oral syringe by drawing water in and out of the syringe using the plunger.



- 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.

Do not throw away the oral syringe.



How Should I Store EPIDIOLEX?

- Store EPIDIOLEX at room temperature between 68°F to 77°F (20°C to 25°C).
- Always store EPIDIOLEX in an upright position.
- **Do not** freeze.
- 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 EPIDIOLEX and all medicines out of the reach of children.**

 Epidiolex®
(cannabidiol)

Helpline Details

For additional assistance, call the toll-free helpline at 1-833-426-4243.

Hours:

Monday–Friday 8:00 AM – 8:00 PM EST

Frequently Asked Questions

- Q: What if there are air bubbles in the oral syringe?**
A: Push the liquid back into the bottle and repeat **Step 5** until the air bubbles are gone.

- Q: What should I do if the liquid in the bottle has turned cloudy?**
A: The liquid in the bottle may turn cloudy if water gets in the bottle. This does not change the safety or how well the medicine works. Continue to use the cloudy liquid as prescribed by your healthcare provider.

Always make sure the oral syringes are completely dry before each use.

- Q: What should I do if the oral syringe is not completely dry before use?**
A: If the oral syringe is not completely dry, use the spare syringe provided in the pack.

 Jazz Pharmaceuticals.

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This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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