

Package leaflet: Information for the patient

Epidyolex 100 mg/ml oral solution cannabidiol

Read all of this leaflet carefully before you or the patient start taking this medicine because it contains important information for you or the patient

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Epidyolex is and what it is used for.
2. What you or the patient need to know before taking Epidyolex.
3. How you or the patient should take Epidyolex.
4. Possible side effects.
5. How to store Epidyolex.
6. Contents of the pack and other information.

1. What Epidyolex is and what it is used for

Epidyolex contains cannabidiol, a medicine which can be used to treat epilepsy, a condition where someone has seizures or fits.

Epidyolex is used in combination with clobazam or with clobazam and other antiepileptic medicines to treat seizures that occur with two rare conditions, called Dravet syndrome and Lennox-Gastaut syndrome. It can be used in adults, adolescents and children of at least 2 years of age.

Epidyolex is also used in combination with other antiepileptic medicines to treat seizures that occur with a genetic disorder called tuberous sclerosis complex (TSC). It can be used in adults, adolescents and children of at least 2 years of age.

2. What you or the patient need to know before taking Epidyolex

Do not take Epidyolex

- if you are allergic to cannabidiol or any of the other ingredients of this medicine (listed in section 6).
- if your doctor determines that you have certain abnormal liver blood tests.

Warnings and precautions

Talk to your doctor or pharmacist before taking Epidyolex or during treatment if:

- you have or have had liver problems, as your doctor may need to change the dose of Epidyolex or may decide that Epidyolex is not appropriate for you.
Your doctor may do blood tests to check your liver before you start taking this medicine and during treatment, as Epidyolex can cause liver problems. If your liver is not working properly, your treatment may need to be stopped.
- you notice unusual changes in your mood or behaviour or have thoughts of harming or killing yourself. **Contact your doctor or go to a hospital straight away** (See section 4).

- Epidyolex can make you feel sleepy. Do not drive, operate machinery, or take part in activities that require you to be alert and have fine control, such as cycling, until you know how Epidyolex affects you.
- you stop taking Epidyolex suddenly.
- your seizures happen more often, or if you experience a severe seizure while taking Epidyolex. **Contact your doctor or go to a hospital straight away.**
- you experience weight loss or are unable to gain weight. Your doctor will monitor your weight and will evaluate if Epidyolex treatment should be continued.

Children and adolescents

Epidyolex is not recommended for use in children under the age of 2 years.

Other medicines and Epidyolex

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Taking Epidyolex with certain other medicines may cause side effects, affect how the other medicines work, or affect how Epidyolex works. Do not start or stop other medicines without talking to your doctor or pharmacist.

Tell your doctor if you are taking any of the following medicines, as your dose may need to be adjusted:

- other epilepsy medicines, such as carbamazepine, clobazam, lamotrigine, lorazepam, phenytoin, stiripentol and valproate, that are used to treat seizures
- other medicines used to treat TSC, including everolimus or tacrolimus
- medicines used to treat acid reflux (heartburn or acid regurgitation) such as omeprazole
- mitotane (a medicine used to treat tumours in the adrenal gland)
- morphine or diflunisal (medicines used to treat pain)
- efavirenz (a medicine used to treat HIV/AIDS)
- theophylline (a medicine used to treat asthma)
- caffeine (a medicine for babies who need help breathing)
- propofol (an anaesthetic used for people undergoing surgery)
- simvastatin, fenofibrate, gemfibrozil, (medicines used to reduce cholesterol/lipids)
- enzalutamide (a medicine to treat prostate cancer)
- bupropion (a medicine to help stop smoking or for treating obesity)
- St. John's wort (*Hypericum perforatum*) (a herbal medicine used to treat mild anxiety)
- medicines to treat bacterial infections, such as rifampin, clarithromycin and erythromycin

Epidyolex with food

Always take Epidyolex according to your doctor's instructions and consistently either with or without food, including high-fat meals (such as ketogenic diet). If you take Epidyolex with food, a similar meal type (e.g., similar fat content) should be taken if possible. (See also section 3, How to take Epidyolex).

Pregnancy, breast-feeding and fertility

If you are pregnant, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. You should not take Epidyolex while you are pregnant unless the doctor decides the benefits outweigh the potential risks.

You should not breast-feed whilst taking Epidyolex, as Epidyolex is likely to be present in breast milk.

Driving and using machines

Talk to your doctor about driving, using machines or when children undertake activities such as cycling or other sports, because you may feel sleepy after taking this medicine.

You should not drive, use machines or take part in activities that require you to be alert and have fine control, until it is established that your ability to perform such activities is not affected.

Epidyolex contains sesame oil, alcohol (ethanol), strawberry flavour components (including benzyl alcohol).

Epidyolex contains refined sesame oil which may rarely cause severe allergic reactions.

Each ml of Epidyolex contains 79 mg of ethanol equivalent to 10% v/v anhydrous ethanol, i.e., up to 691.3 mg ethanol per maximal single Epidyolex dose (12.5 mg/kg) for an adult weighing 70 kg (9.9 mg ethanol/kg). For an adult weighing 70 kg, this is equivalent to 17 millilitres (ml) of beer, or 7 ml of wine per dose.

This medicine contains 0.0003 mg/ml benzyl alcohol corresponding 0.0026 mg per maximal Epidyolex dose (Epidyolex 12.5 mg/kg per dose for an adult weighing 70 kg). Benzyl alcohol may cause allergic reactions.

3. How you or the patient should take Epidyolex

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Epidyolex is an oral solution (a liquid to be swallowed). Your doctor and pharmacist will tell you how much (number of ml) Epidyolex to take each day, how many times a day you should take it and which syringe you should use for your dose (1 ml or 5 ml).

Your doctor will calculate the dose according to your body weight. You may start on a low dose that your doctor gradually increases over time. Contact your doctor if you are unsure of your dose or if you think your dose may need to be changed.

Taking Epidyolex with food can increase the amount of medicine your body takes in. You should try, as far as possible, to take Epidyolex consistently either with or without food, and according to your daily routine, so you get the same effect each time. If you take Epidyolex with food, a similar meal type (e.g., similar fat content) should be taken if possible.

If necessary, Epidyolex may be taken via a nasogastric or gastrostomy tube. Your doctor will give you directions how to do so. Check with your doctor or pharmacist if you are not sure.

Tell your doctor if you have liver problems because the doctor may need to adjust the dose.

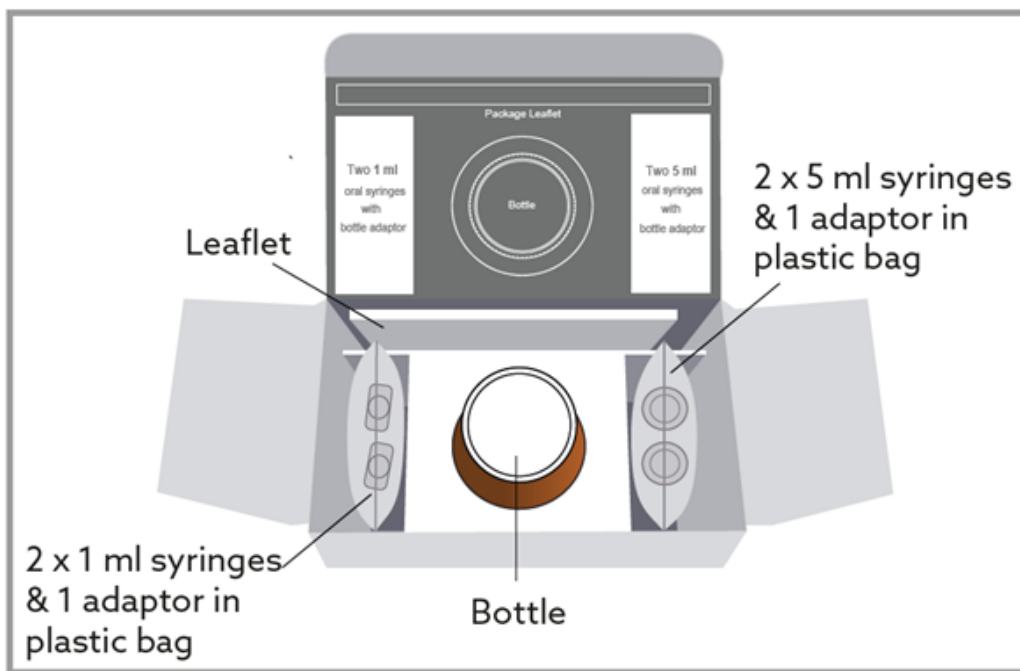
Do not reduce the dose or stop this medicine unless the doctor tells you to.

Instructions for the oral use of Epidyolex

The pack contains the following items

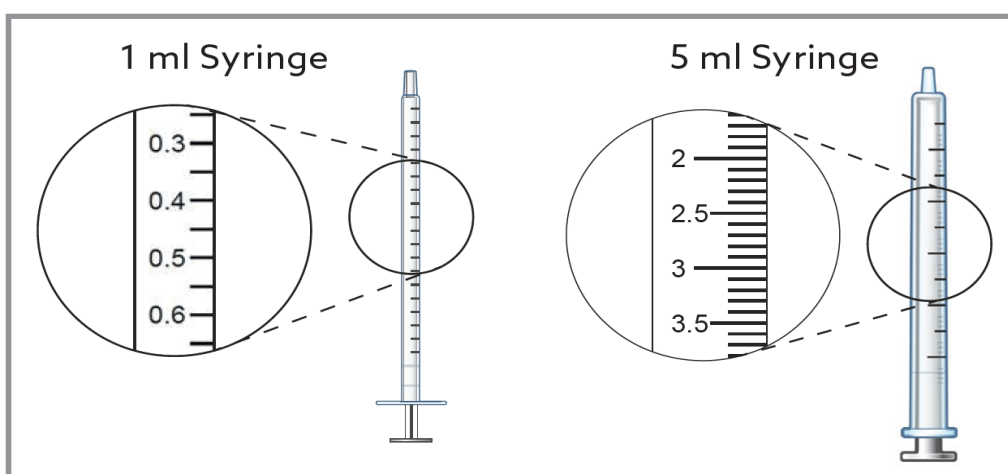
- Epidyolex oral solution bottle
- A plastic bag containing two 1 ml oral syringes and a bottle adaptor
- A plastic bag containing two 5 ml oral syringes and a bottle adaptor

A spare syringe of each size is provided in the pack in case the first one is damaged or lost.

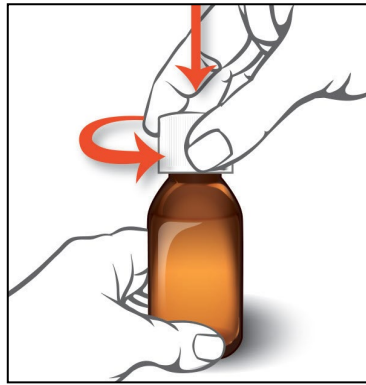


1. Open the bag containing the correct oral syringe to measure your dose.
 - If your dose is **1 ml (100 mg) or less**, you should use the smaller 1 ml syringe.
 - If your dose is **more than 1 ml (100 mg)**, you should use the larger 5 ml syringe.
 - If your dose is **more than 5 ml (500 mg)**, you will need to use the larger 5 ml syringe more than once. In this case, keep careful track of how many times you have filled the syringe (e.g., by marking off each 5 ml dose, respectively) so that you take the right dose.

It is important that you use the correct oral syringe to measure your dose. Your doctor or pharmacist will let you know which syringe to use depending on the dose that has been prescribed. Following the directions from the doctor or pharmacist, the bag containing the other syringes and adaptor should be discarded from the pack unless your doctor or pharmacist tells you to keep both syringes until your final dose has been reached.



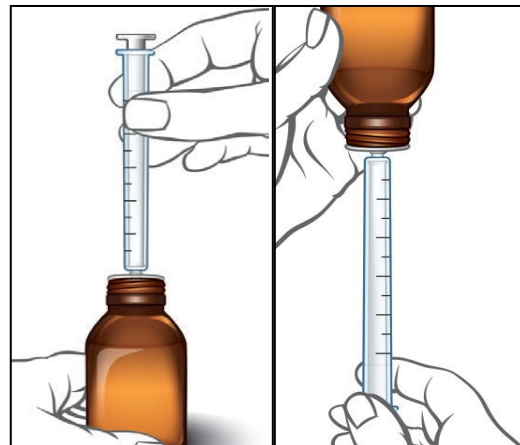
- Remove the child-resistant cap on the bottle by pushing the cap down whilst turning the cap anti-clockwise.



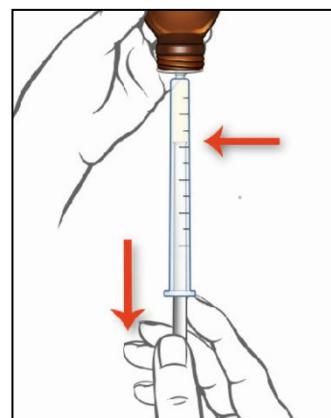
- Push the bottle adaptor firmly into the neck of the bottle, and make sure it is fully inserted. The adaptor could come off and cause choking if it is not fully inserted.



- Insert the tip of the correct oral syringe fully into the bottle adaptor, and with the oral syringe in place, turn the bottle upside down.

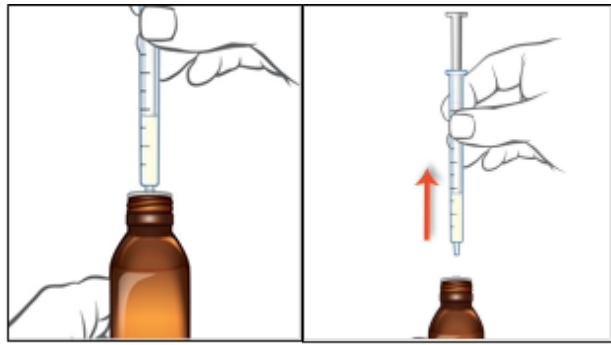


- Slowly pull back the plunger of the syringe, so the volume (number of ml) of solution needed is drawn into the syringe. Line up the end of the plunger with the volume marking required, as shown opposite.

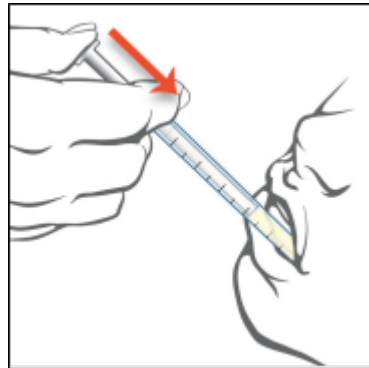


If there is an air bubble in the syringe, push the liquid back into the bottle whilst keeping the bottle upside down, and repeat Step 5 until the bubble has gone.

6. Turn the bottle the right side up, and carefully remove the oral syringe from the adaptor.



7. Place the tip of the oral syringe inside the cheek, and gently push the plunger to release the medicine. Do not push the plunger forcefully or direct the medicine to the back of the mouth or throat.

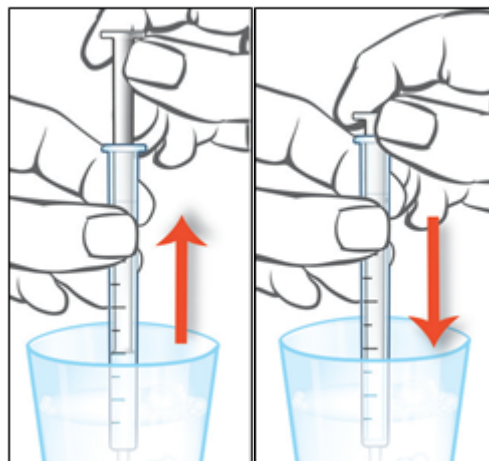


If the dose is more than 5 ml, repeat Steps 4 to 7 to give the remaining dose using the 5 ml oral syringe.

8. Screw the child-resistant cap back on the bottle tightly, by turning the cap clockwise – you do not need to remove the bottle adaptor, as the cap will fit over it.



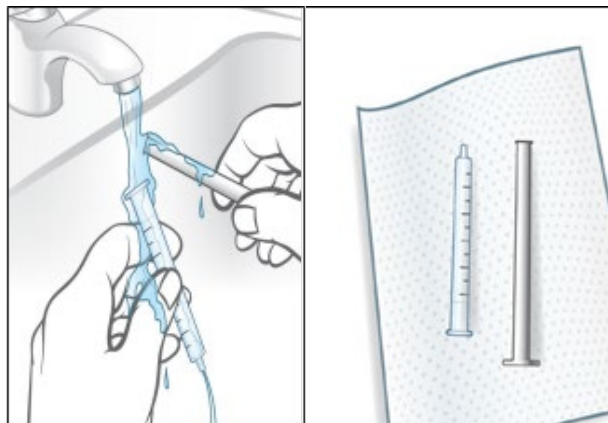
9. Fill a cup with warm soapy water and clean the oral syringe by drawing water in and out using the plunger.



10. Remove the plunger from the barrel of the syringe, and rinse both parts under tap water. Do not place the oral syringe in a dishwasher.

Shake off any water from both parts and allow them to dry in the air until the next use. Make sure the oral syringe is completely dry before the next use, or it could make the solution appear cloudy if water gets in the bottle.

If the solution in the bottle has turned cloudy, this doesn't change how well it works. Continue to use the medicine as normal.



If you or your patient take more Epidyolex than you should

If you may have taken more Epidyolex than you should, tell a doctor or pharmacist immediately, or contact your nearest hospital casualty department, and take the medicine with you.

Signs of taking more Epidyolex than you should include diarrhoea and sleepiness.

If you or your patient forget to take Epidyolex

If you forget to take a dose, do not take a double dose to make up for a forgotten dose. Take the next dose at your regular time. If you miss many doses, please talk to your doctor about the correct dose to take.

If you or your patient stop taking Epidyolex

Do not reduce the dose or stop taking Epidyolex without first talking to your doctor. The doctor will explain how to gradually stop taking Epidyolex.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects could be **very serious**:

- High liver enzymes (transaminases elevations) seen in blood tests, which can be a sign of liver injury, have been reported in patients receiving Epidyolex
- People taking this medicine can have thoughts of harming or killing themselves. If you have these thoughts at any time, contact your doctor

You may get the following side effects with this medicine. Tell the doctor if you have any of the following:

Very common side effects (may affect more than 1 in 10 people):

- feeling drowsy or sleepy
- diarrhoea
- decreased appetite
- fever
- vomiting
- feeling tired

Common side effects (may affect more than 1 in 100 people):

- blood tests showing increases in levels of certain liver enzymes
- seizures
- feeling bad-tempered (irritable, aggressive)
- rash
- lack of energy
- cough
- pneumonia
- weight loss
- feeling sick
- urinary tract infection

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#). By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Epidyolex

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date shown on the bottle. The expiry date refers to the last day of that month.

If you have any solution left in the bottle more than 12 weeks after it was first opened, you should not use it.

This medicine does not require any special storage conditions.

Do not throw away any medicine in the wastewater or household waste. Ask your pharmacist about how to throw away any medicine that you no longer use. This will help protect the environment.

6. Contents of the pack and other information

What Epidyolex contains

- The active substance is cannabidiol. Each ml of oral solution contains 100 mg of cannabidiol.
- The other ingredients are refined sesame oil, anhydrous ethanol, sucralose and strawberry flavour (including benzyl alcohol)

What Epidyolex looks like and contents of the pack

Epidyolex is a clear, colourless to yellow oral solution. It comes in a bottle which has a child-resistant cap, together with two identical 5 ml or 1 ml oral dosing syringes and two bottle adaptors for using these syringes. The 5 ml syringes are graduated in 0.1 ml and the 1 ml in 0.05 ml increments.

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This leaflet was last revised in 01/2022.

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: <http://www.ema.europa.eu>. There are also links to other websites about rare diseases and treatments.