
Patient information

Epidyolex® 100 mg/ml, oral solution

cannabidiol

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of the section on "What side effects can Epidyolex cause?" for how to report side effects.

Information for Patients

Read this leaflet carefully before you start taking or using this medicine. This medicine has been prescribed for you personally. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

Keep this leaflet. You may need to read it again.

In this leaflet:

- 1. What Epidyolex is and what it is used for?**
- 2. What you need to know before you Take Epidyolex?**
- 3. How to use Epidyolex?**
- 4. Possible side effects**
- 5. How to store Epidyolex**
- 6. Further information**

1. What Epidyolex is and what it is used for?

Subject to prescription by a doctor.

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 other antiepileptic medicines to treat seizures that occur with the rare conditions, called Dravet syndrome (DS), Lennox-Gastaut syndrome (LGS), or the tuberous sclerosis complex (TSC).

It can be used in adults, adolescents and children of at least 2 years of age.

2. What you need to know before you Take 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.

Warning 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 have symptoms of a respiratory tract infection such as fever, chills, cough, feeling short of breath or feeling drowsy or sleepy.
- 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 « What side effects can Epidyolex have? »).
- This medicine may affect responsiveness and the ability to drive and use tools or machines. Talk to your doctor about driving, using machines or when you undertake activities such as cycling or other sports, because you or the patient may feel sleepy after taking this medicine. Epidyolex can make you feel sleepy. Do not drive, operate machinery or take part in activities that require you to be alert and react quickly, such as cycling, until you know how Epidyolex affects you.
- If you stop taking Epidyolex suddenly.
- If 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.**

Children and adolescents

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

Concomitant use of Epidyolex with other medicines

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 that can affect how the other medicines work or affect how Epidyolex works. Do not start or stop any 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, midazolam, 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 (used to treat tumours in the adrenal gland)
 - morphine or diflunisal (medicines used to treat pain)
 - efavirenz (used to treat HIV/AIDS)
 - theophylline (used to treat asthma)
 - caffeine (a medicine for babies who need help breathing)
 - propofol (an anaesthetic used for people undergoing surgery)
 - simvastatin, fenofibrate, gemfibrozil (used to reduce cholesterol/lipids)
 - enzalutamide (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

Concomitant use of 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) (see also section «How to use Epidyolex»). If you take Epidyolex with food, a similar meal type (e.g. similar fat content) should always be taken as far as possible.

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

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

This medicine contains 7.9 Vol.-% ethanol (alcohol), i.e., up to 691 mg ethanol per maximal Epidyolex single dose (12.5 mg/kg for an adult weighing 70 kg).

The low quantity of alcohol in this medicine has no noticeable effect.

This medicine contains 0.0003 mg/ml benzyl alcohol corresponding to 0.0026 mg per maximal Epidyolex single dose (12.5 mg/kg for an adult weighing 70 kg).

Benzyl alcohol may cause allergic reactions.

Do not use this medicine for longer than one week in small children (below 3 years of age) except on the advice of your doctor or pharmacist.

If you are pregnant or breast-feeding, ask your doctor or pharmacist for advice, since large quantities of benzyl alcohol can accumulate in your body and cause side effects (so-called « metabolic acidosis »).

If you suffer from liver or kidney disease, ask your doctor or pharmacist for advice, since large quantities of benzyl alcohol can accumulate in your body and cause side effects (so-called «metabolic acidosis»).

Tell your doctor or pharmacist if you

- suffer from other diseases,
- have any allergies or
- are taking or outwardly applying any other medicines (including those bought over the counter).

Can Epidyolex be used during pregnancy or breast-feeding?

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 your doctor decides that the benefits outweigh the potential risks.

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

3. How to use 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 or 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 will gradually increase 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 drug 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 always be taken as far as possible.

If necessary, Epidyolex may be taken via a nasogastric or gastrostomy tube. Your doctor will give you detailed 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.

If you or your patient take more Epidyolex than you/your patient should

If you or your patient may have taken more Epidyolex than you should, tell a doctor or pharmacist immediately, or contact your nearest hospital emergency 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 or your patient 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 or your patient 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.

Instructions for the oral use of Epidyolex

See at the end of this leaflet.

Do not change the prescribed dose on your own initiative. If you think that the effect of the medicine is too weak or too strong, talk to your doctor or pharmacist.

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 (elevated transaminases) 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 your 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
- malaise
- urinary tract infection

If you notice side effects, especially any side effects not listed in this leaflet, you should tell your doctor or pharmacist.

5. How to store Epidyolex

Keep out of the reach of children. Do not use this medicine after the expiry date ("EXP") stated on the container. The expiry date refers to the last day of that month. Store below 30°C. Do not freeze.

Period of use after first opening

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

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

6. Further information

Your doctor or pharmacist can give you more information. These individuals possess the comprehensive Information for healthcare professionals.

What Epidyolex contains?

Epidyolex is a clear, colourless to yellow oral solution. It comes in a bottle with 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 syringes are graduated in 0.05 ml increments.

Active substances

The active substance is cannabidiol. Each ml of oral solution contains 100 mg of cannabidiol.

Excipients

The other ingredients are refined sesame oil, anhydrous ethanol, sucralose and strawberry flavour (containing benzyl alcohol).

What Epidyolex looks like and contents of the pack

Epidyolex is a Clear, colourless to yellow solution One 100 ml bottle

Two 1 ml oral syringes and one bottle adaptor

Two 5 ml oral syringes and one bottle adaptor

Marketing authorisation holder

Jazz Pharmaceuticals Switzerland GmbH, Grafenauweg 8 6300 Zug, Switzerland.

Manufacturer

Jazz Pharmaceuticals Operations UK Limited, Unit 740 Kent Science Park, Sittingbourne ME9 8AG
United Kingdom.

This package leaflet was last revised in October 2022.

To report any side effect(s):

Kingdom of Saudi Arabia:

The National Pharmacovigilance Centre (NPC):

SFDA Call Center: 19999

E-mail: npc.drug@sfd.gov.sa

Website: <http://ade.sfda.gov.sa>

United Arab Emirates:

Emirates Drug Establishment

United Arab Emirates

Email: pv@ede.gov.ae

Tel: 80033784

Kuwait:

Kuwait Ministry of Health Drug and Food

Control Pharmaceutical and Herbal

Medicines Registration and Control Administration

Phone: +965 (4829287-24847475)

Fax: +965 24847477

E-Mail: ADR_reporting@moh.gov.kw

Other GCC States:

Please contact the relevant competent authority.

Epidyolex® may not be registered in all the GCC countries

This is a Medicament

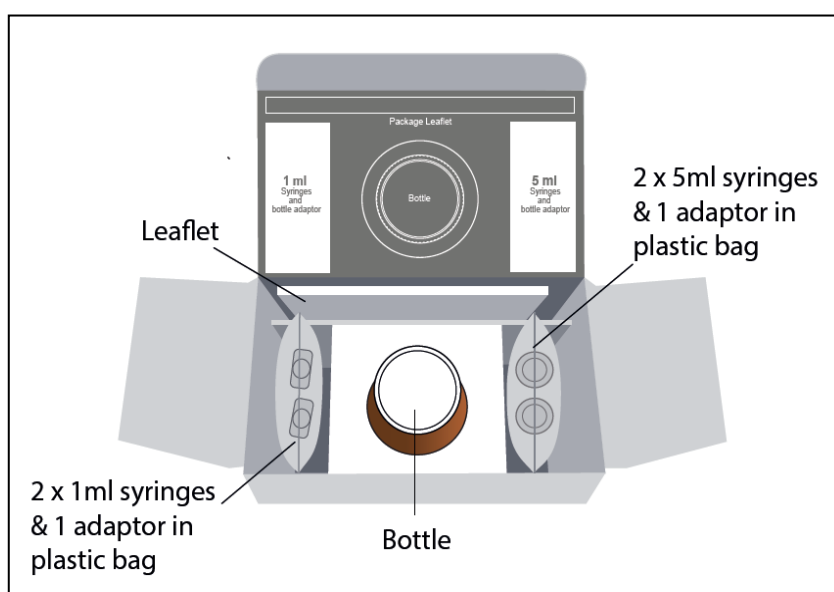
- A Medicament is a product, which affects your health, and its consumption, contrary to instruction, is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not, by yourself, interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor. Keep medicaments out of the reach of children.

Instructions for the oral use of Epidyolex

The pack contains the following items:

- A bottle with Epidyolex oral solution
- 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

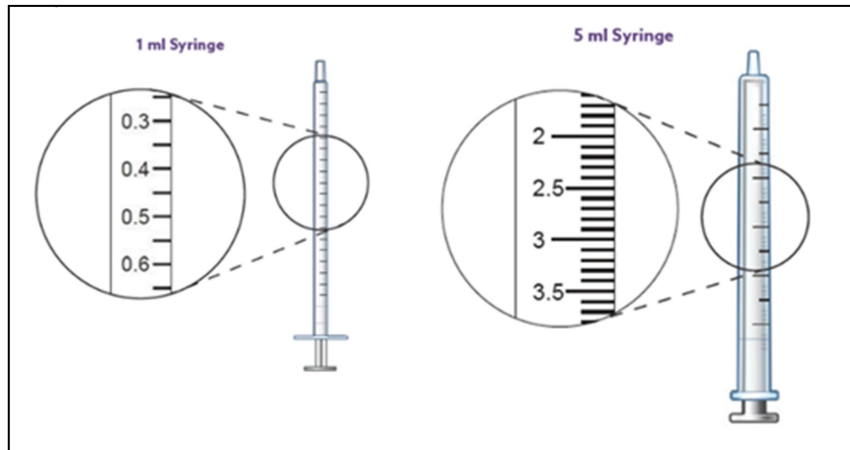
A spare syringe of each size is provided in the pack in case the first one is damaged or lost.



1. Open the bag containing the correct dosing 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) so that you take the right dose.

Following the directions from the doctor or pharmacist, the bag containing the other dosing syringes and adaptor should be removed from the pack and discarded unless your doctor or pharmacist tells you to keep both dosing syringes until your final dose has been reached.



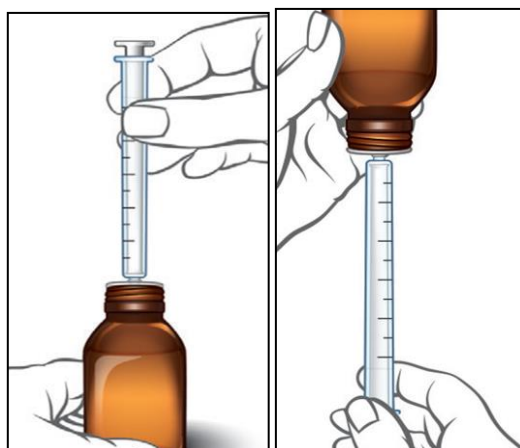
2. Remove the child-resistant cap on the bottle by pushing the cap down whilst turning the cap anti-clockwise.



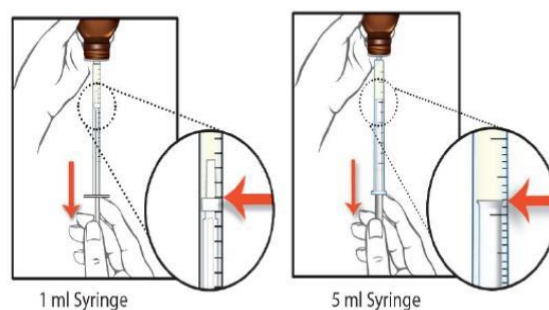
3. Push the bottle adaptor firmly into the neck of the bottle, and make sure it is fully inserted. The adaptor could come off and cause choking if it is not fully inserted.



4. 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.

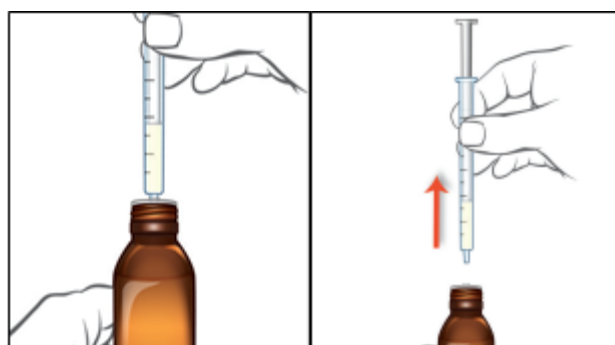


5. Slowly pull back the plunger of the syringe, so the volume (number of ml) of solution needed is drawn into the syringe. Line up the end of the plunger with the volume marking required (as shown opposite).



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.

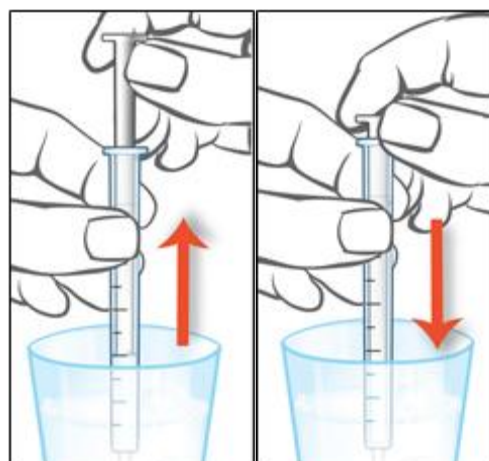
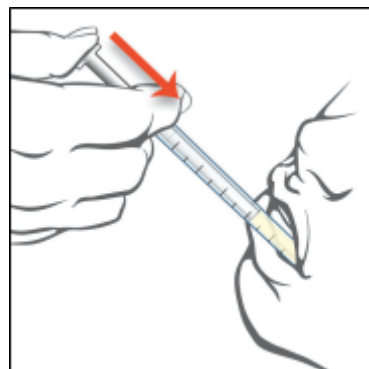


7. Place the tip of the oral syringe inside the cheek, and gently push the plunger to release the medicine. Do not push the plunger forcefully or direct the medicine to the back of the mouth or throat.

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

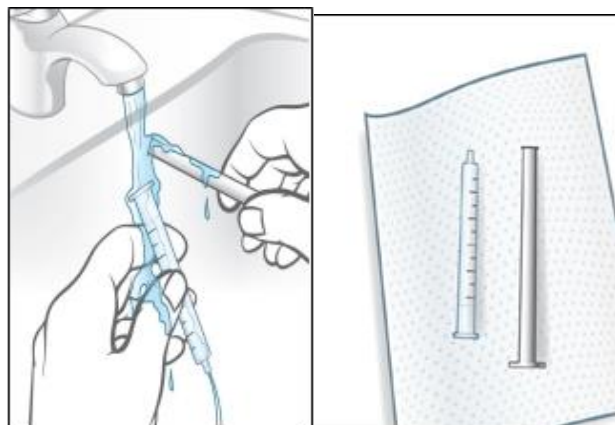
8. Screw the child resistant cap back on the bottle tightly, by turning the cap clockwise – you do not need to remove the bottle adaptor, as the cap will fit over it.

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.