



Cannabidiol (CBD) & Tetrahydrocannabinol (THC) oil

This leaflet contains important information about cannabidiol and Tetrahydrocannabinol oils and should be read before starting the medicine. Keep the leaflet in case you need to read it again.

- Ask your clinician should you have further questions
- This medicine is for you and should not be given to others as it could cause harm
- If you get any side effects (even those not listed in this leaflet) inform your doctor

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Cannabidiol and Tetrahydrocannabinol what are they and what are they used for?

Cannabidiol and Tetrahydrocannabinol are two known active ingredients in cannabis plant extracts which when used as a medicine can be used to treat a range of conditions:

- Fibromyalgia
- Neuropathic pain
- Appetite disorder
- Chemotherapy induced nausea and vomiting
- Palliative care
- Crohn's disease
- Ulcerative colitis
- Epilepsy
- Migraine
- Multiple sclerosis
- Parkinson's Disease
- Anxiety
- Depression
- Insomnia
- Obsessive compulsive disorder & post-traumatic stress disorder
- And more...

Things to know before taking your medicine

Do not take your medicine:

- if you are allergic to cannabidiol, tetrahydrocannabinol or any of the ingredients in the medicine (listed on the product or product leaflet).
- if your clinician indicates that you have certain abnormal liver blood tests or another reason, do not use this medicine.

Warnings and precautions

Speak to your clinician if:

- you have or have ever had liver problems, as the dose of your medicine(s) may need to be adjusted or may need to be withheld altogether. You may be asked to have blood tests to check the function of your liver
- you notice unusual changes in your mood or behaviour or have thoughts of harming or killing yourself. Immediately contact your clinician or go to an Accident and Emergency Department.
- your medicine makes you feel sleepy, affects your ability to concentrate or you experience any of loss of consciousness. Do not drive, operate machinery, or take part in activities that require you to be

alert and have fine control. Your ability to undertake these tasks are more likely to be affected when starting treatment or changing doses.

- you do not take this medicine as prescribed by clinician or you stop taking your medicine. You should not stop your medicine suddenly as some patients have experienced a withdrawal reaction when using high doses of THC. The signs are: anxiety, decreased appetite, weight loss, irritability, restlessness and disturbances in sleep onset and duration. Symptoms can occur 24 hours after stopping, peak in 2-3 days and may last 2-3 weeks.
- your underlying illness gets worse on taking your medicines, contact your doctor or go to a hospital.
- you have a history of substance misuse. 9% of recreational cannabis users have been shown to become dependent. The potential for medical cannabidiol/tetrahydrocannabinol oil to cause addiction is low especially as part of a structured treatment program where THC levels are much lower than used recreationally.
- You have serious heart problems: angina, heart attack, poorly controlled high blood pressure or irregular heartbeat.

The medicine should not be given to children below 2 years, since there is little information on use in this age group. This medicine can be used with caution in children as it is known that high levels of THC can affect the developing brain. Children and adolescents using cannabis recreationally have been shown to be more likely to experience mental health problems in early adulthood.

Other medicines and cannabidiol (CBD) /tetrahydrocannabinol (THC)

Tell your clinician if you are taking, have recently taken or might take any other medicines. Taking cannabis based medicinal products with other particular medicines may cause side effects, affect how other medicines work, or affect how cannabidiol/ tetrahydrocannabinol works. This means that treatment with other medicines may need to be adjusted. Do not start or stop other medicines without talking to your prescribing clinician.





Tell your clinician if you are taking any of the following medicines for example:

- Epilepsy: Carbamazepine, Clobazam, Lamotrigine, Lorazepam, Phenobarbital, Diazepam, Midazolam, Phenytoin, Stiripentol Valproate, Topiramate, Rufinamide, Zonisamide And Eslicarbazepine
- Acid Reflux (Heartburn or Acid Regurgitation): Omeprazole
- Antiplatelet or Anticoagulants: Apixaban, Edoxaban, Rivaroxaban, Fondaparinux, Warfarin, Clopidogrel or Heparin Medicines
- Cancer: Mitotane, Dacarbazine, Flutamide, Enzalutamide
- Pain Or Other Sedating Medicines: Morphine or Diflunisal
- HIV/AIDS: Efavirenz, Ritonavir
- Asthma: Theophylline
- Caffeine
- Anaesthetic: Propofol
- High Blood Cholesterol: Simvastatin, Fenofibrate, Gemfibrozil, Atorvastatin
- Stop Smoking or Anxiety: Bupropion
- Mild Depression: St. John's Wort
- Infections: Rifampicin, Clarithromycin or Erythromycin
- Fungal Infections: Itraconazole, Fluconazole, Ketoconazole
- Immunosuppressants: Tacrolimus
- Mental Health Medicines: Amitriptyline, Chlorpromazine, Modafinil, Methylphenidate Or Amphetamines
- Feeling Sick: Granisetron
- Sedatives Or Hypnotics: Diazepam, Lorazepam or Clobazam, Zopiclone, Zaleplon, Zolpidem, Buspirone
- Heart Problems: Bisoprolol, Propranolol
- Steroids For Inflammation: Hydrocortisone, Beclomethasone, Prednisolone
- Hormones: Ethinylestradiol, Levonorgestrel or Dydrogesterone

Your medicine with food

Always take your medicines according to your clinician's instructions and consistently either with or without food. Large changes in fat content in your meals can affect how your medicine is absorbed.

Your medicine with alcohol

Alcohol reaches all parts of the brain and can affect many things e.g. thinking, reactions and breathing. Your medicine could make the adverse effects of alcohol worse. It is not safe to drive after drinking alcohol, with or without your medicine.

Your medicine and driving

Your medicine can cause drowsiness and initially can reduce your reaction times especially if you take alcohol or other sedatives at the same time, increasing your risk of having an accident, putting yourself and others at risk. If you are taking medicines the rules about driving will depend on the country you're driving in.

Medicines and driving in the UK

<https://www.gov.uk/drug-driving-law>

Having a car accident may mean a statutory defence may apply where cannabis has been legally prescribed by a doctor and driving was not impaired. The THC level needs to exceed legal thresholds. A THC level of over 2 micrograms/L has been judged to be sufficient to exceed the threshold for medical purposes (high medicinal cannabis THC doses may cause this).

It would be best to avoid driving or undertaking tasks that require motor skills to prevent the likelihood of an accident until you know how the medicine affects you. The highest risk for driving would be at the times listed below:

- After a change in dose (especially an increase)
- If you are on a high dose or seem very sensitive to side effects
- If your current medicine causes you blurred vision, drowsiness, poor co-ordination, poor attention.





Your medicine and travelling

Your medicine is a controlled drug in the UK. When carrying your medicine from home, keep it in its original container and keep a copy of your clinic letter securely on your phone or your email should you be questioned by the authorities. Its legal status varies between countries. Check with the embassy of the destination or transit countries before travelling to see if you are allowed to bring your medicine.

Pregnancy, breast-feeding and fertility

If you are pregnant, think you may be pregnant, or are planning to become pregnant, speak to your clinician for advice. You should not breast-feed whilst taking this medicine as it is likely to be present in breast milk.

Allergic reactions

Cannabidiol/tetrahydrocannabinol oils are made using refined oils, some of which may rarely cause severe allergic reactions. Check the product leaflet or label to check the ingredient. Allergy is possible to the pollen and other proteins in the marijuana plant just like you can be allergic to pollen from trees and grasses.

Some cannabidiol/tetrahydrocannabinol oils contain ethanol (alcohol). This should be considered with your clinician in those with a history of alcoholism, pregnant women, children or liver disease.

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How to take your medicine

Your clinician will tell you how much of your medicine to take each day, how many times a day you should take it and how to use an oral syringe.

Your doctor may calculate the dose according to your ideal body weight. You may start on a low dose that your doctor gradually increases over time. Contact your clinician if you are unsure how to take your medicine.

If you forget to take your medicine, start again as soon as you realise, unless it is within a few hours of your next dose. Don't take two doses at the same time to make up for this. If you are worried, please speak to your clinic and ask for guidance.

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Side Effects

This medicine can cause side effects in some people. Should you experience them contact your clinician and document it in the UK cannabis registry. You should tell them about side effects that are not listed overhead.

The following side effects could be very serious, you should seek help immediately if you experience them:

- High liver enzymes (transaminases elevations), which can be a sign of liver damage (signs include: abdominal pain, unexplained nausea and malaise, darkening of urine or jaundice).
- People taking this medicine can have thoughts of harming or killing themselves.

Side Effects

Tell your clinician if you experience any of the possible following side effects (or others not listed):

Common side effects (more than 1 in 100 people)	Very common side effects (more than 1 in 10 people)
Lack of energy or giddy	Feeling drowsy or sleepy
Blurred vision	Decreased appetite
Eating more than usual	Diarrhoea
Difficulty speaking	Fever
Change of taste or dry mouth	Feeling tired
Constipation	Vomiting or nausea
Cold, sore throat/mouth	
Respiratory Tract Infections (Pneumonia, Bronchitis)	
Blood tests showing increases in levels of certain liver enzymes or damage to the liver (signs include: Abdominal pain, unexplained nausea and malaise, darkening of urine or jaundice)	
Shaking, of the body or parts of it	
Feeling bad-tempered (Irritable, Aggressive)	
Difficulty sleeping	
Cough	
Rash	
Increased appetite or weight loss	
Sialorrhea (Drooling)	
Urinary Tract Infection	
Abnormal behaviours or agitation	
Loss of balance or falling over	
	Uncommon (affecting less than 1 in 100 people)
	Fainting
	Changes in pulse rate, heart rate or blood pressure
	Tummy pain
	Mouth or teeth changing colour

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Storing your medicine

- Keep this medicine out of the sight and reach of children in a cool dry place (or as directed on the packaging of the medicine).
- Do not use this medicine after the expiry date on the pack.
- Return any unwanted medicines to a pharmacy.
- Store your medication in its original container.

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Contents of the pack and licensing

The active substance is CBD or THC (or both). The strength of the medicines may be found on the packaging. There are other ingredients that may be found on the bottle or with the package leaflet.


Sativex® is a brand of this medicine. Sativex is licensed in the UK for spasticity in MS. Use of this medicine for other indications would be unlicensed or 'off-label'. Sativex tastes of peppermint and also contains alcohol and propylene glycol.

Some cannabidiol/ tetrahydrocannabinol oils do not have a licence for use in the UK or Europe. These medicines may be made in the UK (known as a special) or may be imported from abroad.

Your clinician will discuss the unlicensed nature of the use of your medicine and will explain the side effects. Your clinician accepts responsibility for prescribing for these uses. Contact your prescriber should you have any further questions before starting your medicine.

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