

Package Leaflet: Information for the user

Read all of this leaflet carefully before you start taking this product because it contains important information for you.

It is important to note that cannabis and cannabis-based products which do not have a marketing authorisation have not been subjected to the same rigorous safety, quality and efficacy standards that are in place for medicines, nor are the producers of such cannabis-based products subject to the same responsibilities as the marketing authorisation holders for authorised medicines.

This leaflet is not specific to the cannabis based product you have been prescribed but it contains some general information about cannabis based products for medical use, which may be helpful. If you have any specific concerns on the use of your cannabis based product, please refer back to your doctor for expert advice.

The Medical Cannabis Access Programme

The context and the source of the clinical information on the use of cannabis-based products comes from the literature on both authorised cannabis-based medicines and cannabis-based products that are not authorised as medicines. The target patient population primarily includes those under the care of a medical consultant, with the following medical conditions:

- spasticity associated with multiple sclerosis resistant to all standard therapies;
- intractable nausea and vomiting associated with cancer chemotherapy, despite the use of standard anti-emetic regimens;
- severe, refractory (treatment-resistant) epilepsy that has failed to respond to standard anticonvulsant medications.

Cannabis-based products are not intended as first-line treatment for these conditions.

What you need to know before you start taking this product

Do not start treatment if you:

- are allergic to cannabis, THC, CBD or any of the other ingredients listed on the label of this product
- have severe and unstable cardio-pulmonary disease (angina, peripheral vascular disease, cerebrovascular disease, and arrhythmias) or have risk factors for cardiovascular disease
- have a current, active drug dependence, including illegal drugs, alcohol, and prescription medications
- have current untreated schizophrenia or psychosis
- are currently taking cannabis based products, cannabis based medicines or using cannabis recreationally
- are currently pregnant, or breastfeeding as considerable levels of cannabinoids are likely to be present in maternal breast milk and there are potential impacts on a foetus or infant

Warnings and precautions

Talk to your doctor or pharmacist before taking this product if you:

- are aged 18 years old and under because of the potential effects of THC on the developing brain (for products that contain THC)

- have a personal or family history of schizophrenia or any psychotic disorder
- have severe liver or renal disease
- have previous drug dependence, including illicit drugs, nicotine, alcohol and prescription medications
- are planning to become pregnant or during pregnancy unless the potential risks to the foetus and/or embryo are considered to be outweighed by the benefit of treatment. There is insufficient experience in humans regarding the effects of cannabis on the reproduction. Therefore, men, and women of child bearing potential, should take reliable contraceptive precautions for the duration of therapy and for three months after discontinuation of therapy. Reports of pre-term labour and low birth weight have been associated with cannabis use.
- are taking other medications, especially sedatives such as opioids and benzodiazepines and medicines metabolised by cytochrome p450 isoenzymes
- are elderly, as breakdown of the product in the elderly is slower. It is likely older patients will be more sensitive to the pharmacological effects of cannabis.

Other medicines and cannabis based products

There is a possibility of a clinically significant interaction between other prescription or over the counter medicines you may be taking and cannabis-based products.

Care should be taken with hypnotics, sedatives, and medicines with potential sedative effects, as there may be additive effects on sedation and muscle relaxing effects.

Care should be taken when co-administering cannabis-based products with anti-spasticity agents, as a reduction in muscle tone and power may occur, leading to a greater risk of falls and injury.

There may be a potential for interaction between cannabis for medical use and disease modifying treatments for multiple sclerosis.

CBD can interact with other epilepsy medicines, causing levels of those medicines in the blood to rise. This means that patients should be carefully monitored for side effects and to ensure that their drug levels remain therapeutic and do not enter the toxic or harmful range. For example, elevated levels of clobazam, and its active metabolite, have been reported in children with refractory epilepsy treated with CBD (Geffrey et al, 2015). Therefore, monitoring of clobazam levels is necessary for the clinical care of patients concomitantly treated with clobazam and CBD.

Additional list of possible interactions with cannabis NOTE:

This list is not exhaustive.

Group	Examples of Medicines
Alcoholic beverages and medicines used in alcohol dependence	Naltrexone
Amphetamine	

Anti-anxiety, hypnotics and sedatives	Barbiturates Narcotic analgesics including codeine and morphine Benzodiazepines including clobazam, diazepam and triazolam Duloxetine
Anti-coagulants	Warfarin
Anticholinergic	Atropine Ipratropium
Anti-depressants	Selective serotonin reuptake inhibitors, for example, fluoxetine; tricyclic antidepressants and amitriptyline.
Anti-epileptics	Clobazam Carbamazepine Eslicarbazepine Midazolam Phenytoin Phenobarbital Sodium valproate Topiramate Zonisamide
Anti-infectives	Ketoconazole Itraconazole Clarithromycin Rifampicin Erythromycin
Anti-psychotics	Chlorpromazine
Anti-spasticity, muscle relaxants	Baclofen Tizanidine
Herbal medicine	St John's Wort
Mood stabilisers	Lithium
Non-steroidal anti-inflammatories	Ibuprofen Naproxen
Protease inhibitors	Indinavir Nelfinavir Ritonavir
Proton pump inhibitors	Lansoprazole Omeprazole
Phosphodiesterase inhibitors	Sildenafil Vardenafil Theophylline
Statins	Atorvastatin Simvastatin
Others	Digoxin Everolimus Melatonin Oestradiol Progesterone Aprepitant

Alcohol and cannabis based products

Cannabis may interact with alcohol (ethanol), affecting coordination, concentration and ability to respond quickly. In general, alcoholic beverages should be avoided whilst using cannabis-based medicines or products, especially at the beginning of treatment or when changing dose. Patients should be advised that if they do drink alcohol while using cannabis the additive effects on the brain may impair their ability to drive or use machines and increase the risk of falls and injury.

Effects on your ability to drive and use machines

Cannabis may produce undesirable effects such as dizziness and drowsiness which may impair judgement and performance of skilled tasks. Patients should not drive, operate machinery or engage in any hazardous activity if they are experiencing any significant central nervous system (CNS) effects such as dizziness or drowsiness.

The Road Traffic Act 2016 provides for medical exemption certificates for patients prescribed cannabis for medical use containing THC. Doctors and patients should familiarise themselves with the clinical and driving effects of cannabis for medical use as well as the drug testing regime in Ireland. Further information can be obtained at www.rsa.ie

How to take cannabis based products

Follow the instructions as detailed on the label, as prescribed by your doctor. Supplementary information is provided below. Speak to your doctor before stopping or altering your dose.

All such products should be taken following the information provided by your doctor or pharmacist. However, in the absence of dosage information, the general recommendation is to 'start low and go slow'. Specific recommendations are:

- commence treatment at the lowest possible dose
- first doses should be given in the evening to assist with management of side effects, and the patient should be advised to have someone with them
- the dose should be increased slowly, at intervals of between 1 and 4 weeks, until a satisfactory dose is reached
- monitor carefully for side effects upon initiation and on an ongoing basis.

Doses depend on the type of product used, individual variation, the development of tolerance, interaction with other drugs and previous exposure to cannabis, either recreationally or medically. Lower doses are less likely to be associated with side effects.

Where dosage information is not provided on dispensing of the product, a person should seek guidance from their pharmacist or refer back to their doctor.

Time to onset of effect

Cannabis-based products taken by mouth, such as oils or liquid capsules, are more slowly absorbed than products administered by other routes. They take at least 30 to 90 minutes before any effects are felt. Peak effects can occur two to four hours after consumption. Given the longer time frame for peak effects, it is important to allow at least three hours between administration of single oral doses to avoid possible overdose. Effects can last for up to eight hours and as long as 24 hours. This may be of particular importance in relation to the timing of systemic anticancer treatment in order to get the maximum benefit.

If you take too much or forget to take a dose, speak with your doctor or pharmacist as soon as possible for guidance.

Transferring to another cannabis-based product or medicine, withdrawal from treatment, and discontinuation of therapy

If your doctor transfers you from one cannabis-based medicine or product to another, your dose may need to be adjusted again, starting at a low dose, depending on the composition of the medicine or product. Different cannabis products have the

potential for different side effects and interactions. Speak with your doctor or pharmacist if you have any concerns.

The symptoms associated with the withdrawal of treatment include irritability, difficulty sleeping, decreased appetite and anxiety. Gradual withdrawal of treatment is recommended, unless abrupt discontinuation is required for safety reasons.

Speak with your doctor before stopping or altering your dose.

Possible side effects

Cannabis based medicine or products can cause side effects. Listed below are some known side effects associated with approved medicines which contain cannabis, but these may differ from the product you have been prescribed under the Medical Cannabis Access Programme, as the products are different and contain different ingredients. If you get any suspected side effects, please talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

Cannabis based medicines

Side effects associated with approved cannabis based products or medicines are more likely to occur when your treatment first starts. In most cases side effects are quite mild and they generally wear off within a few days.

As a guide, side effects of approved cannabis based medicines include the following, but this list is not exclusive:

Very common (affecting more than 1 in 10 people)

- Feeling dizzy or tired.

Common (affecting less than 1 in 10 people)

- Feeling depressed or confused.
- Feeling over-excited or losing touch with reality.
- Problems with your memory or having trouble concentrating.
- Feeling sleepy or giddy.
- Blurred vision.
- Eating more or less than usual.
- Changed sense of taste or a dry mouth.
- Constipation or diarrhoea.
- Feeling or being sick.
- Lack of energy or feeling weak or generally unwell.
- Feeling abnormal or drunk.
- Loss of balance or falling over.

Uncommon (affecting less than 1 in 100 people)

- Seeing or hearing things that are not there (hallucinations).
- Believing ideas that are not true.
- Feeling that other people are against you.
- Thoughts of suicide.
- Fainting.
- Changes in pulse rate, heart rate or blood pressure.
- Tummy pain.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; Email: medsafety@hpra.ie. By reporting side effects, you can help provide more information on the safety of this product.

Foreign travel

Before going abroad, check that it is legal for you to take this product with you.

This includes any countries you are travelling through.

Cannabis is a controlled drug in many countries and its legal status will vary between countries.

Driving while taking Cannabis might be illegal in some countries.

How to store this cannabis based product

Please store this product as per the instructions on the label. Keep this product out of the sight and reach of children.

Do not use this product after the expiry date which is stated on the label.

Do not use this product if you notice a change in colour or odour, or any other visible signs of deterioration.

Do not throw away any products via wastewater or household waste. Ask your pharmacist how to dispose of product you no longer use. These measures will help protect the environment.

This leaflet was last revised **July 2019**.

Other sources of information

Name and address of the supplier is available on the product label.

Further information on the Medical Cannabis Access Programme, including the [Clinical guidance on cannabis for medical use](#), is available on www.health.gov.ie

The cannabis products permitted to be prescribed under the programme are listed in Schedule 1 of the Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) Regulations 2019, available at www.health.gov.ie