

**PATIENT INFORMATION LEAFLET:**  
**INFORMATION FOR THE USER**

**Unlicensed Cannabis-based Product for Medicinal Use (CBMPs) – Dried Cannabis**

You have been given this information as you have been prescribed an unlicensed Cannabis-based Product for Medicinal Use (CBPM) from Spectrum Therapeutics™ by your doctor. Read all of this leaflet carefully before you start using this medicine because it contains important information for you. 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.
- Dosage and administration instructions are provided by your treating doctor according to the specific circumstances of your treatment.

**DISCLAIMER**

Spectrum Therapeutics' CBPMs are provided as unlicensed medicinal products. **These products have not been granted marketing authorisation in the UK. This means they have not been assessed by the MHRA for safety, quality and efficacy.** Therefore, treatment must always be carried out under close supervision by a specialist physician, with patients being closely monitored especially when treatment is initiated.

**What Is In This Leaflet?**

1. Spectrum Dried Cannabis Products
2. How to Take Your Medicine
3. Knowing the Risks
4. Warnings & Precautions
5. How to Store Spectrum Dried Cannabis Products

**1. Spectrum Dried Cannabis Products**

Your doctor will have prescribed one of the Spectrum Therapeutics™ Dried Cannabis Products below. Your prescription will provide you with a dose (in g) you should take. Following the instructions provided by your doctor, the information in this leaflet helps ensure you are administering it correctly and receiving the prescribed dose of THC and CBD

**Spectrum Therapeutics Dried Cannabis Products**

Product	Red No 4	Red No 2	Blue
Origin	<i>Cannabis sativa</i>	<i>Cannabis sativa</i>	<i>Cannabis sativa</i>
THC	22% w/w	18% w/w	8% w/w
CBD	<0.5% w/w	<0.5% w/w	7% w/w

The products are offered as dried cannabis ("bud"). The plant material consists of individual flowers and flower organs which present in a brown-green colour. Whole flowers from the female cannabis plant are harvested, the stem and leaves are trimmed to remove most of this material. The flowers are then dried to a specific moisture content.

The amount of THC and CBD in the product is presented on the product label as a percentage of the weight (% w/w). This allows your physician to calculate the quantity, in grams, to use each time for you to achieve the desired dose.

**2. How To Take Your Medicine**

Your doctor will have discussed the appropriate product and dose for you to start with. The key message is to 'Start Low and Go Slow'. You will have been prescribed a CBPM for vaporizing

**Vaporizing:** When inhaling vaporized dried cannabis the active ingredients are absorbed almost immediately into your bloodstream through the lungs, and the effects usually last 2 to 4 hours. A vaporizer heats cannabis without burning it so that the active compounds are released into a vapour for inhalation, minimising exposure to the by-products from combustion. Smoking cannabis is not recommended.

The product should be weighed using a scale which can measure to at least 0.1g accuracy. Every effort should be made to use the same vaporizer each time. Spectrum recommend that a vaporizer carrying the CE mark is used. Your treating physician or pharmacist should advise you on the vaporizer to use and assist with ensuring consistency of dosing.

### **3. Knowing the Risks**

When using CBPMs especially for the first time, you may experience some of the following:

- Increased heart rate
- Dizziness
- Impaired co-ordination and reaction times
- Drowsiness
- Impaired short-term memory
- Dry mouth
- Nausea
- Anxiety
- Cough and/or respiratory irritation (for products intended for inhalation)
- Increased appetite
- Euphoria
- Diarrhoea and/or abdominal discomfort (for products intended for ingestion)

Adverse effects are experienced most when you take your first dose and, after feeling no immediate apparent effect, decide to take more. Avoid taking more than one dose within a short period of time, and no more than is recommended by your doctor. Where you have been advised to increase your dose over time, follow the instructions from your doctor carefully. It could take a week or longer to determine your ideal dose, but this will also help to minimise side effects.

Be sure to tell your doctor which prescription, non-prescription, or herbal products you are currently taking. Cannabis may interact with several medications, particularly any drugs that slow down the central nervous system, causing drowsiness.

Consult your doctor or pharmacist immediately if during treatment you experience chest pain, anxiety, nausea, dizziness, vomiting, or fainting.

Stop use and call your doctor if you experience an allergic reaction (skin rash, hives, itching, swelling of eyes, face, lips, tongue, or throat, wheezing or breathing difficulties).

**It is important to note that these products are unlicensed in the UK.** The list of adverse effect agrees with guidance used in Canada<sup>1</sup> where the products are produced. The list of adverse effects applies to cannabis-based products in general. It is not product-specific and has not been reviewed by regulators in the UK. If you get any side effects, it is important to inform your doctor or pharmacist immediately. This includes any possible side effects which are listed in this leaflet as well as any that are not. You can also report side effects directly to the UK Medicines and Healthcare Products Regulatory Agency (MHRA) via the Yellow Card Scheme - [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

### **4. Warnings and Precautions**

- This medicine may make you feel drowsy.
- Do not drive if you feel drowsy, dizzy, if you are unable to concentrate or make decisions, or if you have blurred or double vision.
- Do not use tools or machinery if you feel drowsy.
- Do not drink alcohol while taking this medicine.
- Do not use if you are pregnant or breastfeeding.
- Do not use if you know you have allergies to the product or any excipients.

### **5. How to Store Spectrum Dried Cannabis Products**

The product should be stored below 25°C in the original container. Protect the product from moisture, direct light, excessive heat or cold. Do not freeze.

The product must be kept out of reach and sight of children.

#### **Manufacturer:**

Canopy Growth  
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68789  
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#### **References:**

1. Information For Healthcare Professionals: Cannabis And The Cannabinoids. Health Canada. Spring 2018.