little

Australian medicinal cannabis

Australia's first producer of medicinal cannabis.





Product selection guide for Healthcare Professionals



Medical grade cannabis





Continuous supply since 2018



AU GMP manufactured products





Australian made





Full plant extract flower & oral solutions

CBD : THC explained

POTENTIAL EFFECTS OF CONSTITUENTS

The THC: CBD ratio helps prescribers identify which products may treat their patient's condition most effectively.

Potential effects of CBD & THC ^{1,2}					
CBD (Cannabidiol)	THC (Tetrahydrocannabinol)				
Analgesic	Analgesic				
Anti-inflammatory	Anti-inflammatory				
Anti-convulsive	Anti-convulsive				
Antiemetic	Antiemetic				
Sleep Assistance	Sleep Assistance				
Neuroprotective	Neuroprotective				
Appetite Stimulation	Appetite Stimulation				
Reduces the intoxicating effect of THC	Intoxication				
Anti-anxiety/Anti-depressant					
Improved cognition					

RESEARCH

Evidence supports the use of the following ratios of CBD and THC in the treatment of:

INDICATION	CBD DOMINANT	BALANCED	THC DOMINANT
Anorexia ³⁻⁸	\bullet	\bullet	
Anxiety 9-10	•		
Autism 11	•	O ADULT	
Cachexia 4-8		•	•
Cancer pain & symptom management ^{7-8,12}		•	•
Chronic Pain 13-16	•		
CINV ^{7, 17-18} Chemo Induced Nausea & Vomiting		•	•
Depression 6	\bullet	•	
Fibromyalgia 19-21		•	\bullet
IBS ²²⁻²⁴	•	•	ightarrow
Insomnia 6-7, 10, 25-26	•	•	ightarrow
Neuropathic Pain 14, 27-28		•	ightarrow
Parkinson's Disease 29-31		•	ightarrow
PTSD 25, 32	•		ightarrow
Refractory Epilepsy 33-38		O ADULT	
Seizure Management ³³⁻³⁸	•	O ADULT	
Spasticity, MS ^{13, 27, 39-42}		•	•

Israel Ministry of Health Cannabis Guidelines³

Please note the evidence provided generally relates to cannabis treatment using the named active ingredients and is not be taken as specific evidence for the efficacy of any listed products.

There are important considerations for each method ⁴³ (adapted from MacCallum, Russo, 2018):

OVERVIEW	OIL	BUCCAL SPRAY	VAPORISATION
ONSET	60-180 minutes	15-45 minutes	5-10 minutes
DURATION	6-8 hours	6-8 hours	2-4 hours
ABSORPTION	From the GI tract and metabolized in the liver before entering the bloodstream.	From transmucosal absorption directly into the bloodstream.	Through the lungs directly into bloodstream.
+ PRO	Discreet, convenient, odorless, beneficial for chronic conditions / symptoms where control over longer periods of time is sought.	Faster onset of action than oil.	Beneficial for acute or episodic symptoms.
CONS	Titration difficulty due to delayed onset of action.	Inconsistent dispensing	There are two TGA approved vaporisation devices (as at April 2021). Devices may be expensive, may not be portable and require patient mobility.

CANNABIS OILS

Oil based products are the preferred and most common method of administration in Australia. As advised by the TGA, "Given the slower onset and longer duration, it is expected that taking medicinal cannabis products orally would be more useful for medical conditions or symptoms where control over longer periods of time is sought similar to the use of slow release medications".⁴³

Cannabis oil is made by extracting concentrated resin from the cannabis flower, and diluting the resin with a pharmaceutical grade oil. The finished oil product has a defined concentration measured in mg of THC and mg of CBD per mL of oil.

CANNABIS FLOWER

Cannabis flower is growing in popularity amongst experienced prescribers and is typically used for acute conditions like breakthrough pain. Flower is often prescribed in combination with a prescribed cannabis oil.

Current product range: LGP CLASSIC OIL & FLOWER

This product range is locally produced using full plant extract medicinal cannabis. Our Classic range has a variety of THC and CBD ratios presented in a simple oil formulation. For assistance on which product to consider please contact our Medical Team.

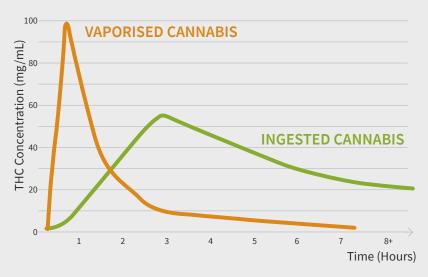
RANGE	PRODUCT NAME	SCHEDULE	THC (MG/ML)	CBD (MG/ML)	SIZE	TOTAL CANNABINOIDS	PRICE	PRICE
		OIL - F	ULL PLANT EX	TRACT				PER mg
	LGP CLASSIC CBD 50	4	<0.2 mg	50 mg	50 mL	2500 mg	\$225	\$0.09
CBD / CBD DOMINANT RANGE	LGP CLASSIC 1:100	8	<1.5 mg	100 mg	50 mL	5050 mg	\$295	\$0.05
	LGP CLASSIC 1:20	8	1 mg	20 mg	50 mL	1050 mg	\$175	\$0.17
BALANCED RANGE	LGP CLASSIC 10:10	8	10 mg	10 mg	50 mL	1000 mg	\$175	\$0.17
THC DOMINANT RANGE	I GP CLASSIC 2015		20 mg	5 mg	50 mL	1250 mg	\$175	\$0.17
	DRIED CANNABIS FLOWER						PER g	
THC DOMINANT RANGE	LGP FLOWER THC DESERT FLAME	8	22% w/w	<1%w/w	15g	N/A	\$255	\$17

Colours to identify THC:CBD ratios

Little Green Pharma uses colours to help identify our products' primary active ingredients. Either the dominant cannabinoid OR the actual amount of THC or CBD is indicated in our oil product name following the industry standard which is to present THC content first.



ONSET AND DURATION OF INHALED VS ORAL MEDICINAL CANNABIS



Reference: Grotenhermen F. "Some practice-relevant aspects of the pharmacokinetics of THC". Forsch Komplementarmed. 1999 Oct; 6 Suppl 3:37-9.

Application support & education for practitioners

Please contact Little Green Pharma for assistance with:

- Application support via the TGA's SAS application pathway
- Evidence to support the use of medicinal cannabis for a particular condition
- Education and training
- Authorised Prescriber application assistance

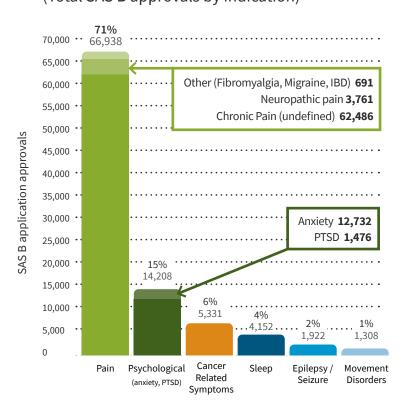
Contact us: medical@lgpharma.com.au or 1300 118 840

MOST COMMON CONDITIONS BEING APPROVED VIA SPECIAL ACCESS SCHEME*

- 1 Chronic Pain 13-16
- 2 Anxiety 9-10
- 3 Cancer pain and symptom management ^{7-8, 12}
- 4 Insomnia 6-7, 10, 25-26
- 5 Neuropathic pain 14, 27-28
- 6 Post Traumatic Stress ^{25, 32}
- 7 Seizure management ³³⁻³⁸
- 8 Epilepsy 33-38
- 9 Fibromyalgia 19-21
- 10 Parkinon's Disease 29-31

FIG.1

Indications (as at 1 March 2021) (Total SAS B approvals by indication)



Source: TGA SAS B Scheme, Freedom Of Information, disclosure - FOI 2275, published 1 April 2021 Special Access Scheme Category B pathway specific to medicinal cannabis products during the period 1/11/2016 to 1/03/2021). https://www.tga.gov.au Over 215 conditions approved

Over 130,000 approvals

for SAS B medicinal cannabis applications (June 2021)

We help with SAS B applications

Accessing medicinal cannabis

The most common way a medical practitioner can apply to prescribe a medicinal cannabis product for a single patient is through the Special Access Scheme (SAS) Category B at compliance.health.gov.au

An approval letter from the TGA (and in some instances, your State health department) is required for Schedule 8 medicinal cannabis products before they can be prescribed. Schedule 4 products (CBD only) require only a TGA approval.

Dosing Guidelines: **START LOW, GO SLOW**

The TGA recommends a 'start low and go slow' approach to dosing in line with international guidelines.^{43,45} Dosing remains highly individualised and relies on each patient to work with their medical practitioner to find the dose that works best for them. The rate, speed of dose adjustment and total daily dose will depend on individual response.

Oil medication - Dosing example only

CBD product: LGP CLASSIC CBD 50

	DAY 1-3	DAY 4-6	DAY 7-9	DAY 10-12	DAY 13-15	DAY 16-18
Morning	Nil	0.50 mL	0.50 mL	0.75 mL	0.75 mL	1 mL
(C) Evening	0.50 mL	0.50 mL	0.75 mL	0.75 mL	1 mL	1 mL

Balanced: LGP CLASSIC 10:10 CBD dominant: LGP CLASSIC 1:20 and 1:100

	DAY 1-3	DAY 4-6	DAY 7-9	DAY 10-12	DAY 13-15	DAY 16-18
Morning	Nil	0.25 mL	0.25 mL	0.50 mL	0.50 mL	0.75 mL
(C) Evening	0.25 mL	0.25 mL	0.50 mL	0.50 mL	0.75 mL	0.75 mL

THC dominant: LGP CLASSIC 20:5

	DAY 1-3	DAY 4-6	DAY 7-9	DAY 10-12	DAY 13-15	DAY 16-18
Morning		0.1 mL	0.1 mL	0.15 mL	0.15 mL	0.25 mL
(C) Evening	0.1 mL	0.1 mL	0.15 mL	0.15 mL	0.25 mL	0.25mL

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WHAT TO EXPECT WITH CANNABIS OIL



PLEASE NOTE:

Older patients and children may be more sensitive to cannabinoids and need lower dosing. In the majority of patients, the daily dose of THC does not exceed 30mg. Please ask Little Green Pharma for more information.

Flower medication - Example only for vaporisation

THC dominant: LGP FLOWER THC - Desert Flame (22% w/w THC :<1% w/w CBD)

	DAY 1-3	DAY 4-6	DAY 7-9	DAY 10-12	DAY 13-15	DAY 16-18
Morning	Nil	0.1g	0.1g	0.1g	0.15g	0.15g
() Midday		Nil	0.1g	0.1g	0.1g	0.15g
Evening	0.1g	0.1g	0.1g	0.15g	0.15g	0.15g

DOSING⁴⁵

It is recommended patients vaporising LGP Flower start with 1 inhalation, wait 15 minutes, and then increase by 1 inhalation every 15-30 minutes until clinical effect and as tolerated, ensuring the recommended maximum daily dose is not exceeded. Titrate from a start dose of 0.1g to where clinical effect occurs with a maximal dose of 1g per day*. Recommend using a TGA-approved vaporizer device. **Daily limits apply to THC in WA*.

Dosing remains highly individualised and relies on each person finding the dose that works best for them where the benefits are maximised and unwanted adverse effects are minimised. The rate and speed of dose adjustment will depend on individual response. The TGA recommends a 'start low, go slow' approach, in line with international dosing guidelines.⁴⁶⁻⁴⁷





Patients should continue to titrate until therapeutic benefits are maximised and unwanted side effects are minimised.





COMMON SIDE EFFECTS OF MEDICINAL CANNABIS⁴⁵

SIDE EFFECT	Most Common	Common	Rare
Drowsiness/ fatigue			
Dizziness or feeling light headed	\bullet		
Dry mouth, throat irritation			
Cough, phlegm, bronchitis (smoking only)			
Anxiety			
Nausea	\bullet		
Cognitive effects			
Euphoria			
Blurred vision			
Headache			
Orthostatic hypotension			
Toxic psychosis/ paranoia			\bullet
Depression			
Ataxia/ dyscoordination			•
Tachycardia (after titration)			
Cannabis hyperemesis			\bullet
Diarrhoea			

DRUG INTERACTIONS 1, 47-48

- Drugs metabolised by CYP450
- Warfarin and other blood thinners (THC and CBD can increase the levels of these drugs in the system)
- Use with alcohol, barbiturates and benzodiazepines (increased central nervous system depressive effects)
- Clobazam (CBD can increase levels)
- Theophylline (THC and CBD can decrease levels)

DRUGS IMPACTING THC AVAILABILITY DRUGS THAT POTENTIATE THC DRUGS THAT INHIBIT THC AVAILABILITY AND INCREASES BIOAVAILABILITY & SIDE EFFECTS AVAILABILITY AND DECREASE ITS EFFECTIVENESS Antidepressants Rifampicin (e.g., fluoxetine, fluvoxamine) Proton pump inhibitors (e.g., omeprazole) Carbamazepine Macrolides Phenobarbital (e.g., clarithromycin, erythromycin) Antimycotics (e.g., itraconazole, fluconazole, Phenytoin ketoconazole, miconazole) Calcium antagonists Primidone (e.g., diltiazem, verapamil) HIV protease inhibitors (e.g., ritonavir) Rifabutin Amiodarone Troglitazone Isoniazid St John's wort

CONTRAINDICATIONS

Medicinal cannabis, including LGP products, should not be used in patients with a history of:

- hypersensitivity to any cannabinoid or to smoke
- severe liver or renal disease.

EFFECTS ON LABORATORY TESTS

Medicinal cannabis, including LGP products, may cause a positive reaction in random drug testing as measurable concentrations of THC can be detected in urine many days after the last dose. It may take up to five days for 80 to 90 percent of the dose to be excreted. Patients should consider any applicable workplace policies.

SPECIAL WARNINGS AND PRECAUTIONS

 Patients must not drive while taking any LGP products or operate machinery as these medications may cause drowsiness (not applicable for LGP Classic CBD 50).

Little Green Pharma products are not recommended for:

- Women who are pregnant, planning to become pregnant or breastfeeding.
- Patients with unstable cardiovascular disease.
- Patients with severe liver or renal disease (TGA Patient Info Guidelines Reference, available here: https://www.tga.gov.au/publication/ guidance-use-medicinal-cannabis-australiapatient-information).
- Patients with a history of psychosis.
- Patients with active mood or anxiety disorder (not applicable for LGP Classic 1:20 or LGP Classic CBD 50).

LGP products should be used with caution in patients:

- With a history of substance abuse, including alcohol abuse, as such individuals may be more prone to abuse cannabis.
- With ongoing chronic hepatitis C should be strongly advised to abstain from daily cannabis use, as this has been shown to be a predictor of steatosis severity in these individuals.
- Receiving concomitant therapy with sedativehypnotics or other psychoactive drugs because of the potential for addictive or synergistic CNS depressant or psychoactive effects.

Considerations & FAQs

Q	Can patient drive or operate machinery?	Please note that the current national legislation is that it's illegal to have THC in your body whilst driving or operating machinery, regardless of impairment levels. LGP Classic CBD 50 is the only product in our range which has undetectable amounts of THC according to independent laboratory testing. As a medical practitioner you are able to prescribe any medicinal cannabis product, however if it contains THC, you should advise your patient to not drive or operate machinery whilst taking this medication. You can contact LGP for a patient consent form.
Q	What about drug testing in the workplace?	A patient can check with their individual workplace to see if holding a current prescription for medicinal cannabis means they are able to have CBD and/ or THC in their system. If no THC is allowed, then LGP Classic CBD50 may be a consideration.
Q	What is a common starting point for patients suffering from pain?	If the patient suffers from chronic pain, a common starting point is a balanced product such as LGP Classic 10:10. However, if the patient is unable to take THC due to above reasons then LGP Classic CBD 50 is a common starting point for many patients.
Q	Has the patient tried illicit cannabis before?	If a patient advises you that they have been smoking or vaping illegally-sourced cannabis flower, then it is likely this product contains high amounts of THC. If the patient has been getting therapeutic effect from this product then you can consider prescribing a medical cannabis product with THC.
		Some patients may advise they have been using CBD only products and seeing positive results. Please note that illegal 'CBD only' products advertise they have no THC, but a recent study found 94% in fact contained detectable THC, and 75% contained almost no CBD at all. If a patient compares a pharmaceutical grade CBD-only medicine with an illicit product it will likely be very different due to the controlled content of active ingredient/s. ⁴⁴
Q	How much medical cannabis is required?	This depends on the product prescribed, the patient's condition and their response to cannabis medicines. An average patient taking LGP Classic 10:10 for chronic pain takes 1-1.5mL per day, meaning a 50mL bottle costing \$175 lasts around 4-6 weeks.
Q	How much does it cost?	The patient will need to consider your consult fees and required monitoring as part of the prescribing process.
		Using the same example above a patient taking 1-1.5mL per day would pay between \$3.50 - \$5.30 (per day) which equates to between \$100 - \$140 per month. However, dosing will vary between patients.
Q	Can the patient buy CBD-only medicine OTC?	In Feb 2021 The TGA down-scheduled certain low dose cannabidiol (CBD) preparations from Schedule 4 to Schedule 3. However, there are currently NO approved CBD products that meet the criteria to be sold over the counter and LGP believes this will unlikely change until 2022. Therefore patients can only access CBD via their prescriber who will use the TGA Special Access or Authorised Prescriber Scheme.
Q	Why choose Little Green Pharma?	At Little Green Pharma the patient is at the centre of everything we do! From our compassionate access scheme offering free medication, to our product pricing and clinical research programs, which offer subsidised products. We are here to make it easier for you to help your patients!



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