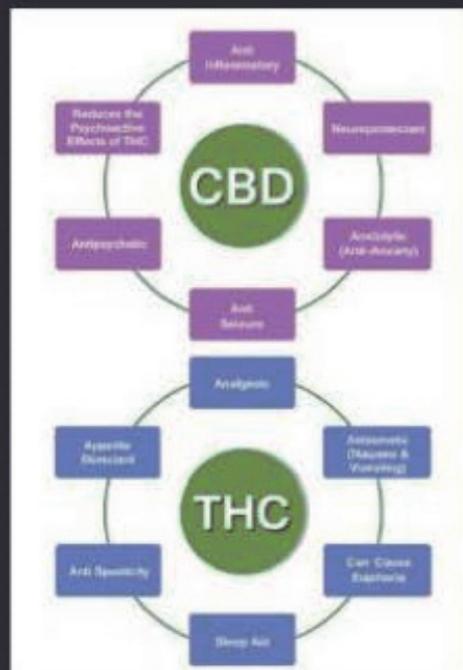


Medical use of cannabis & cannabinoids

- Medical cannabis: "describes products derived from the whole cannabis plant or its extracts that contain a variety of active cannabinoids and terpenes, which patients administer for medical purposes, after consulting with and obtaining authorization from a health care provider"
 - 3 types of cannabinoids: phytocannabinoids (eg. THC, CBD), endocannabinoids, and synthetic cannabinoids (eg. nabilone)
 - Not a single entity but a class of compounds with a variety of potentially pharmacologically active components
- Main active components in cannabis plant products are THC (delta-9-tetrahydrocannabinol) and CBD (cannabidiol)
 - Each chemical variety or **chemovar** (ie. 'strain') varies in the relative amounts of cannabinoids



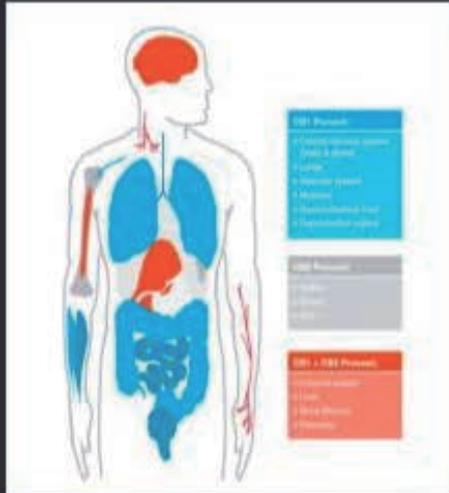
THC:CBD

Each cannabis product will contain THC and CBD, however the THC: CBD ratio will differ depending on the product.

https://www.pharmacists.ca/cpha-ca/assets/File/cpha-on-the-issues/MedicalCannabis_FAQ_Final.pdf

MaoCallum, C and Betts F. Greenleaf Medical Clinic
-Patient Guide to Medical Cannabis (Sep 2017)

The endocannabinoid system



MacCallum C, Betts F. Greenleaf Medical Clinic -Patient Guide to Medical Cannabis (Sep 2017)

- Endocannabinoid signaling at CB1 receptors
 - Mediates ability of endocannabinoids to reduce pain sensitivity and possibly modulates the emotional component of pain
- THC has clear target: CB1 receptors
- CBD however, influences a host of different receptors and systems
- Lack of CB1 receptors in the brainstem cardiorespiratory centres
 - No recorded overdose deaths attributed to medical or recreational cannabis use

Medical vs. recreational cannabis?

- Medical cannabis:
 - Patients generally use cannabinoids to alleviate symptoms while minimizing intoxication
 - CBD-predominant chemovars with the lowest concentration of THC
- Recreational cannabis:
 - Users may use cannabis for euphoric effects
- Critical to maintain a two-stream system for recreational and medical cannabis
 - Patients may have to pay sales or "sin" taxes on cannabis
 - Insured reimbursement of product costs for medical users may be an issue
 - Medical chemovar availabilities may decrease as commercial producers would have more financial incentive to produce recreational 'strains'
 - Lack of medical supervision increases risk of adverse events
 - Funding for medical cannabis research may be negatively impacted
 - Possible stigmatization for healthcare providers who authorize cannabis and for patients who actually have an appropriate indication for medical cannabis



Obtaining medical cannabis in Canada

- Patients do not obtain medical cannabis from pharmacies
 - Must be ordered online from a Health Canada approved licensed producer, which is then mailed directly to the patient's residence, or
 - Patients must register with Health Canada to produce a limited amount of cannabis for their own medical purposes, or
 - Patients designate another individual to produce a limited amount of cannabis for their own medical use
- Each licensed producer has a medical authorization form that requires completion by a physician or nurse practitioner (prescribing regulations vary by province)
 - Authorization document must be completed annually, at a minimum



Pharmacy profession and medical cannabis

- Currently, pharmacists in Canada are not involved in dispensing medical cannabis, nor have the opportunity to provide formal clinical oversight
 - However, some pharmacists are getting involved in providing counselling and support to patients who use medical cannabis
- Canadian Pharmacists Association (CPhA):
 - "Even though pharmacists are not dispensing medical cannabis at this time, it is important for pharmacists to understand how their patients may use and access medical cannabis in order to provide effective medication management. Pharmacists may provide counselling on areas such as contraindications, drug interactions, management of side effects, alternative therapies, potential addictive behaviour, and appropriate use."
- CPhA has developed evidence-based education and resources (eg. evidence guide, product monograph on cannabinoids) to help pharmacists in providing safe and effective education to patients



Our role as pharmacists

Our Role as Pharmacists

- Complete a thorough **screening assessment**
 - Identify patients potentially to benefit from medicinal cannabis
 - Collect patient's medical history
 - Review medication list
 - Assess appropriateness of medical cannabis therapy through screening questionnaire
 - Detect misuse, diversion and disorder through:
 - Opioid Risk Tool (ORT)
 - CAGE Questionnaire (alcohol use disorder assessment)
 - Cannabis Use Disorder Questionnaire (CUDIT-R)
- **Educate** patients
 - Therapeutic use
 - Safe use of cannabis products
- **Answer questions**
 - Dispel myths about cannabis
- Help patients **access** appropriate treatment via medical cannabis use
- Help patients complete registration & treatment agreement form (when applicable)
- **Monitor** patient and optimize medication therapy
- Employ **harm reduction** strategies

Dicm medical cannabis program
2022

Indications and proposed uses

- The National Academies of Sciences, Engineering and Medicine published an extensive review of 10,000 cannabis publications in 2017: *The Health Effects of Cannabis and Cannabinoids*
 - "Conclusive or substantial" evidence for the application of medical cannabis in chronic pain in adults, MS spasticity symptoms, as an antiemetic in CINV, and as a treatment for intractable seizures in Dravet and Lennox-Gastaut syndromes

MacCallum CA, Russo EB. Practical considerations in medical cannabis administration and dosing. *European Journal of Internal Medicine* (2018).

Table 3
Levels of evidence for cannabis-based medicines in various conditions.

Cannabis and cannabinoids supporting evidence	
Level of evidence	Benefits
Conclusive or substantial evidence or efficacy	<ul style="list-style-type: none"> • Adult chronic pain treatment • Multiple sclerosis spasticity symptoms • Chemotherapy-induced nausea and vomiting • Treatment of intractable seizures in Dravet and Lennox-Gastaut syndromes (CEB)
Moderate evidence of efficacy	<ul style="list-style-type: none"> • Improving outcomes in individuals with sleep disturbance associated with chronic pain, multiple sclerosis, fibromyalgia, obstructive sleep apnea syndrome
Limited evidence of efficacy	<ul style="list-style-type: none"> • Decreasing intracranial pressure in glaucoma • Symptoms of dementia • Symptoms of Parkinson disease • Positive and negative symptoms of schizophrenia • Symptoms of posttraumatic stress disorder • Appetite and decreasing weight loss associated with HIV/AIDS • Multiple sclerosis spasticity (distant-evidence) • Traumatic brain injury/intracranial haemorrhage associated disability, mortality, and other outcomes • Symptoms of anxiety in social anxiety disorders (CEB) • Symptoms of Tourette syndrome
Limited evidence of inefficacy	<ul style="list-style-type: none"> • Depressive symptoms in chronic pain or multiple sclerosis patients
Inadequate evidence of efficacy or inefficacy	<ul style="list-style-type: none"> • Addiction/abstinence • Symptoms of irritable bowel syndrome • Cancers, including glioma • Cancer-associated anorexia, cachexia syndrome and anorexia nervosa • Symptoms of amyotrophic lateral sclerosis • Chronic and some neuropsychiatric symptoms associated with Huntington disease • Dystonia

Safety

- **Contraindications and precautions:**
 - Patients under the age of 25
 - ***Exception: indication for CBD in treatment-resistant seizures (patients under the age of 25 may still access medical cannabis in Canada)
 - Personal history or strong family history of psychosis
 - Current or past cannabis use disorder
 - Active substance use disorder (SUD)
 - Uncontrolled cardiovascular (angina, peripheral vascular disease, cerebrovascular disease, arrhythmia) or respiratory disease
 - Pregnant or breastfeeding
 - Cannabis-induced hyperemesis syndrome

- **Substance use disorder/addiction:**
 - Not a true contraindication in cancer patients (may reduce cravings in some SUDs and reduces risk of opioid overdose deaths in jurisdictions where cannabis has been legalized)

Adverse Events

Table 4

Adverse events associated with cannabis-based medicines.

Side effect	Most common	Common	Rare
Drowsiness/lethargy	✓		
Dizziness	✓		
Dry mouth	✓		
Cough, phlegm, bronchitis (Smoking only)	✓		
Anxiety	✓		
Nausea	✓		
Cognitive effects	✓		
Euphoria		✓	
Blurred vision		✓	
Headache		✓	
Orthostatic hypotension			✓
Toxic psychosis/paranoia			✓
Depression			✓
Ataxia/dyscoordination			✓
Tachycardia (after titration)			✓
Cannabis hyperemesis			✓
Diarrhea			✓

MacCallum CA, Russo EB. Practical considerations in medical cannabis administration and dosing. *European Journal of Internal Medicine* (2018).

Drug interactions

- Most drug interactions with cannabis are associated with concurrent use of other CNS depressants
- Clinically significant drug interactions with cannabis are rare but more drug interaction studies need to be conducted
- THC is primarily metabolized in the liver by cytochrome P450 isoenzymes 2C9, 2C19, and 3A4
 - Serum levels may increase with inhibitors or decrease with inducers
 - Theoretically possible drug interactions
- There is an interaction between clobazam and high dose CBD:
 - Results in increased levels of a sedating metabolite, N-desmethyl clobazam
 - Requires dose reduction of clobazam

Routes of administration

Table 2
Administration factors in cannabis delivery methods.

Issue	Smoking/vaporisation	Oral	Oromucosal	Topical
Onset (min)	5–10	60–180	15–45	Variable
Duration (h)	2–4	6–8	6–8	Variable
Pro	Rapid action, advantage for acute or episodic symptoms (nausea/pain)	Less odor, convenient and discrete, advantage for chronic disease/symptoms	Pharmaceutical form (salts/solids) available, with documented efficacy and safety.	Less systemic effect, good for localised symptoms
Con	Dexterity required, vaporisers may be expensive, and not all are portable	Titration challenges due to delayed onset	Expensive, spotty availability	Only local effects

MacCallum CA, Russo EB. Practical considerations in medical cannabis administration and dosing. *European Journal of Internal Medicine* (2018).

Helping patients & physicians complete authorization forms

- The medical document authorizing patient access to cannabis must be completed with the following information:
 - Physician's given name and surname, business address and telephone number, the province in which they are authorized to practice and the number assigned by the province to that authorization, and their fax number and email address (if applicable)
 - Patient's given name, surname, and date of birth
 - Address of the location at which the patient consulted with the physician
 - Daily quantity of dried cannabis, expressed in grams, that the physician authorizes for the patient
 - Period of use, expressed as a number of days, weeks or months which must not exceed one year
- Patient application form is completed by the patient and must include patient's first and last name, date of birth, gender, physical and mailing addresses, and phone number/email address

CanniMed™ Medical Document

100 Pine Lake Blvd, Suite 100, 8900
 1-800-455-7817
 info@cannimed.com
 www.cannimed.ca

8150 St. Charles Blvd, Suite 201, 8900
 1-800-455-7817
 info@cannimed.com
 www.cannimed.ca

Part 1 - Health Care Practitioner Information

First name: _____ Last name: _____
 Profession: _____ Medical license number: _____
 (If not applicable) _____
 Street address: _____
 City: _____ Province: _____
 Telephone: _____ Fax: _____ Email: _____
 Address of your office (if it differs from business address):
 Street address: _____
 City: _____ Province: _____

Part 2 - Patient Information

First name: _____ Last name: _____
 Date of birth: _____ Sex: _____ Gender: Male Female Other

Part 3 - Physician's Prescription

Default will be full product information. Please indicate specific restrictions (if applicable):
 (If Patient Request available as of 10/01/2019 date)

24 grams per day
 Average Authorized Amount For Patient
 per Month (2019)

Submit Medical Document
 Secure fax: 5-866-221-8100

Part 4 - Authorization

I, the Health Care Practitioner, declare that the information provided to CANNIMED, and knowledge from my signed Medical Document is true, correct, and complete to the best of my knowledge, by entering, submitting this Medical Document to the provider as described (online/through or other means).

Health Care Practitioner's signature: _____ Date: _____
 (If covering electronically)

Part 5 - Authorization

I, the Health Care Practitioner, declare that the information provided to CANNIMED, and knowledge from my signed Medical Document is true, correct, and complete.

Health Care Practitioner's signature: _____ Date: _____

For office use only
 Date: _____
 Signature: _____

CanniMed™ Application Form A
 Applicant with a permanent residence

100 Pine Lake Blvd, Suite 100, 8900
 1-800-455-7817
 info@cannimed.com
 www.cannimed.ca

8150 St. Charles Blvd, Suite 201, 8900
 1-800-455-7817
 info@cannimed.com
 www.cannimed.ca

Part 1 - Patient Information

First name: _____ Last name: _____
 Date of birth: _____ Sex: Male Female Other
 Gender: Male Female Other

Part 2 - Contact Information

Medical address - Primary (Physician's office must be in Canada)
 If entering a fax if you have one include your (Patient) residence. If you do not have one, leave blank or enter (Patient) residence.
 Address line 1: _____ Address line 2: _____
 City: _____ Province: _____ Postal code: _____
 Phone: _____ Fax: _____ Cell #: _____
 E-mail address: _____

Mailing address - Applicant's home address:
 Address line 1: _____ Address line 2: _____
 City: _____ Province: _____ Postal code: _____

Part 3 - Shipping address - Please indicate correct return address
 Physical Address Mailing Address

Part 4 - Declaration of Applicant (or the Person Responsible for the Applicant)

I, the applicant, declare that the information provided to CANNIMED, and knowledge from my signed Medical Document is true, correct, and complete to the best of my knowledge, by entering, submitting this Medical Document to the provider as described (online/through or other means).

Signature: _____ Date: _____



Medical Document
To be completed by a Health Care Practitioner. All data reported is subject to verification and is subject to audit.

Patient Information
(PLEASE PRINT NAME, ADDRESS AND CONTACT INFORMATION)

First Name: Last Name:

State of Birth:

Place of Birth: Daily Weight: lbs

Usage Pattern:

Health Care Practitioner Information
(PLEASE PRINT NAME, ADDRESS AND CONTACT INFORMATION)

Title: First Name: Last Name:

Profession:

Business Address:

City: Province: Postal Code:

Consultation Address:

City: Province: Postal Code:

Phone/Fax - Office:

Phone/Fax - Home:

Signature:

Workplace (if applicable):

www.tilray.ca | 1-800-387-0844 (T844) | Fax: 1-800-393-1222



Application to be a Tilray Patient

Patient Information
All data reported under this form is subject to verification and is subject to audit.

First Name: Last Name:

State of Birth:

Gender:

Age:

Residence Address:

City: Province: Postal Code:

Phone/Fax:

Workplace Address:

City: Province: Postal Code:

www.tilray.ca | 1-800-387-0844 (T844) | Fax: 1-800-393-1222

Patient case -CB

Patient	<ul style="list-style-type: none"> 56 year old female with central neuropathic pain (NP) secondary to a spinal cord injury from a motor vehicle accident in 2016
Chief complaint	<ul style="list-style-type: none"> Severe constant neuropathic pain (8 - 9 out of 10) in her left leg with characteristics of shooting, burning, and stabbing, and which is especially worse in the evening (starting at around 2100 hrs) Pain is affecting her sleep (difficulty falling asleep and waking up every 2 hours from pain) and her appetite has decreased significantly (lost ~5 kg in the past month)
History of presenting illness	<ul style="list-style-type: none"> January 2018: patient had a 3 month follow-up appointment with her physician and reported neuropathic pain in left leg averaged 5 -6 out of 10 (moderate severity) March 2018: booked an earlier appointment with physician as pain worsened (as above) and drug therapy was ineffective in controlling her pain
Past medical history	<ul style="list-style-type: none"> Central neuropathic pain Insomnia Depression Irritable bowel syndrome -Constipation (IBS -C)

Patient case -CB

Current medications	<ul style="list-style-type: none"> • Nabilone 0.5 mg TID and 2 mg HS ***patient reports lack of effectiveness and wishes to discontinue*** • Pregabalin 150 mg BID • Duloxetine 60 mg BID • Amitriptyline 75 mg HS • Zopiclone 7.5 mg HS prn • Lorazepam 1 mg HS prn
Past medications	<ul style="list-style-type: none"> • Tramadol 200 mg OD (discontinued Sep 2017 due to constipation) • Acetaminophen/codeine/caffeine 300/30/15 mg- 2 tablets QID (discontinued Jun 2017 due to constipation and daytime sedation) • Tried other opioid medications but discontinued due to constipation and daytime sedation
Allergies	<ul style="list-style-type: none"> • No known drug allergies
Social history	<ul style="list-style-type: none"> • Caffeine: 1 cup of coffee/day • Alcohol: none • Smoker: none • Recreational drug use: currently started purchasing cannabis products from an unauthorized cannabis store (see following slide)

Cannabis products CB uses



Comatose

\$11.00 – \$275.00

Comatose

Category: Indica
 Cross/Genetics: N/A
 Experience Described: Axi: Sleepy, Relaxing, Strong
 Effective For: Pain Relief, Insomnia, Depression
 Related Products: Riverside Purple
 Product Details: This strain is the definition of sleepy! This heavy hitter is perfect for bedtime and its strong sedating effects will relax the mind and body.



IOKO Oil IOG Gardens

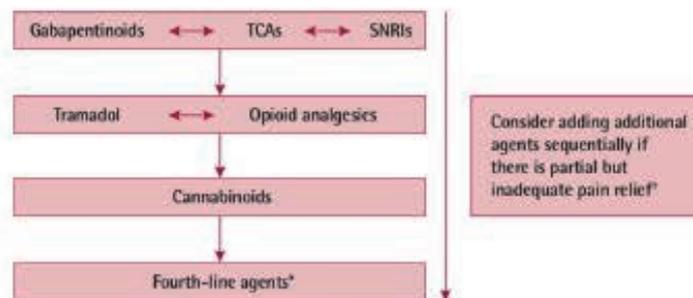
Category: Indica Oil
 Cross/Genetics: Kush Blend
 Experience Described: Axi: Euphoric, Sleepy, Relaxing, Appetite inducing
 Effective For: Insomnia, Chronic Pain, Nausea
 Related Products: Purple Kush Oil, Pink Kush Oil
 Product Details: Can be consumed by dabbing, coating rolling papers, using a vaporizer and orally. Comes in a 1g glass vial.

Drug therapy problems

- CB's neuropathic pain is uncontrolled (severe intensity, shooting/burning/stabbing) secondary to ineffective drug therapy, which has also significantly worsened her sleep (difficulty falling asleep, waking up several times at night) and decreased her appetite (lost ~ 5kg in the past month). She benefits from a reassessment of her drug therapy regimen.
- CB is at risk of experiencing adverse effects (eg. fungal infections in the lungs, GI complications, long-term adverse effects due to unregulated growing conditions of cannabis) secondary to using unregulated cannabis products from an unauthorized source. She benefits from discontinuing use of unregulated cannabis and reassessment of her cannabis use for chronic neuropathic pain.

Canadian guidelines for chronic NP

Figure 1. Algorithm for the pharmacologic management of neuropathic pain



SNRI—serotonin–norepinephrine reuptake inhibitor, TCA—tricyclic antidepressant.
 *Fourth-line agents include topical lidocaine (second-line for postherpetic neuralgia), methadone, lamotrigine, lacosamide, tapentadol, and botulinum toxin.
 †There is limited randomized controlled trial evidence to support add-on combination therapy.
 Adapted from Moulin et al.²

Mu A, Weinberg E, Moulin DE, Clarke H. Pharmacologic management of chronic neuropathic pain. *Canadian Family Physician*. 2017;63:844-52.



Addressing effectiveness of CB's drug therapy

- CB started nabilone in Jan 2018 (0.5 mg BID) but her dose was increased to 0.5 mg TID and 2 mg HS over the past month due to worsening neuropathic pain
- CB reports minimal improvement in pain (reduced by ~1 point on the numeric pain scale) despite the increase in her nabilone dose
- A friend of CB's suggested she try cannabis, which she purchased about 2 weeks ago and self-administered. CB reported that her pain improved by 2 to 3 points after using the flower (fast-acting) and oil (long-acting) products.
- CB wishes to continue using cannabis products and she would like to discontinue nabilone due to a reported lack of effectiveness



Addressing safety of CB's drug therapy

- Cannabis products from unauthorized distributors increases the risk of patients experiencing adverse effects as growing conditions are unregulated (eg. bacterial/fungal growth, pesticide use, etc.)
- Concentrations and proportions of THC and CBD are not standardized and can vary significantly
- CB understands these risks and is interested in switching to using medical cannabis sourced from a Health Canada authorized licensed producer

CanniMed medical cannabis products for CB

- After a meeting with CB and her physician, an informed decision was made for CB to trial the CanniMed 1:20 Oil and 10:10 Oil to help with her pain, sleep, and appetite.
 - Patient preferred not to use vaporized cannabis (flower) yet
- 1:20 Oil (inflammation, pain):
 - THC 1.0 mg/mL & CBD 20.0 mg/mL
- 10:10 Oil (neuropathic pain, insomnia):
 - THC 9.8 mg/mL & CBD 9.9 mg/mL



www.cannimed.ca

Medical cannabis dosing and titration

- There is currently no established, evidence-based dosing guideline for medical cannabis
 - 'Start low, go slow, stay low' approach is recommended
- CanniMed
 - "Patients new to cannabis oil should begin their dose at less than 0.5 mL."
- Cannabinoids: Prescribing Considerations (RxFiles, Oct 2018)
 - Initial: 2 to 3 mg of CBD +/- THC po HS (cannabinoid-naive patients)
 - Usual: uncertain due to lack of randomized trials; titrate slowly
- *Practical considerations in medical cannabis administration and dosing* (MacCallum CA and Russo EB)
 - THC (at bedtime): start at 2.5 mg THC-equivalent QHS (1.25 mg if young, elderly, or other concerns) and increase by 1.25 to 2.5 mg THC after 1-2 days if previous dose tolerated, or
 - THC (daytime): start at 2.5 mg THC-equivalent OD, then increase to 2.5 mg BID after 1-2 days, and increase as needed and as tolerated to 15 mg THC-equivalent divided BID-TID
 - CBD: start at 5 to 25 mg per day divided BID to TID
- No available information on dosage adjustment for renal/hepatic impairment

Tapering and discontinuing nabilone

- A tapering schedule was suggested for CB to discontinue nabilone and to start the CanniMed 1:20 and 10:10 oils
 - CB's current dose of nabilone was 0.5 mg at 0900, 1200, 1500, and 2 mg at 2100
- There is no established evidence-based tapering regimen for nabilone
 - Patients should avoid abrupt discontinuation due to risk of withdrawal symptoms

DAY 1 to DAY 3	
Nabilone	0.5 mg at 1200 and 1500 ***stop doses at 0900 and 2100***
1:20 cannabis oil	0.25 mL at 0900
10:10 cannabis oil	0.25 mL at 2100
DAY 3 to DAY 6	
Nabilone	0.5 mg at 1200
1:20 cannabis oil	0.25 mL at 0900 and 1500
10:10 cannabis oil	0.25 to 0.5 mL at 2100
DAY 7 and ONWARDS	
Nabilone	Discontinued
1:20 cannabis oil	0.25 mL at 0900, 1200, and 1500
10:10 cannabis oil	0.5 to 0.75 mL at 2100

patient to increase cannabis oil dose if pain is not adequately managed (↑ by 0.25 mL TID for 1:20 oil, ↑ by 0.25 mL HS for 10:10 oil as tolerated until pain goal achieved)

Monitoring and follow-up

Effectiveness	Week 1 2	Week 3 4
<ul style="list-style-type: none"> Reduction in pain 	Reduction in pain to ~7/10	Reduction in pain to ~5-6/10
<ul style="list-style-type: none"> Improvement in sleep 	Quicker to fall asleep but waking up every 3-4 hours	Less difficulty in falling asleep and waking up < 2X during the night
<ul style="list-style-type: none"> Improvement in appetite 	Some improvement	Closer to baseline
Safety	Week 1-2	Week 3-4
<ul style="list-style-type: none"> Drowsiness/fatigue 	Absent	Absent
<ul style="list-style-type: none"> Dizziness 	Absent	Absent
<ul style="list-style-type: none"> Cardiac effects (eg. tachycardia, postural hypotension) 	Absent	Absent

Ongoing care for CB

- CB's pain severity at weeks 3-4 follow-up was ~5-6/10 (moderate) and she reported improvement in the shooting/burning/stabbing symptoms
 - CB's pain goal: 3-4/10
- There was still room to increase her dose as she had tolerated both the 1:20 and 10:10 cannabis oils very well
 - Suggested she could increase her dose by 0.25 to 0.5 mL every 3 days until pain manageable and goal reached
- Most patients use 1 to 3 g of herbal cannabis per day (<5% use > 5 g per day)
 - 1 g = 6 mL of cannabis oil
 - 3 g = 18 mL of cannabis oil
- Patients do not develop tolerance to benefits and dose escalation over time is usually not observed
- Continue monitoring for adverse effects with CB increasing her doses and monitor for signs and symptoms of cannabis use disorder

Frequently asked questions

- Cannabis use disorder
 - 9% of adults who use cannabis recreationally may develop addiction
 - Up to 17% if started in adolescence
 - Cannabis Use Disorder Identification Test - Revised (CUDIT-R)
- How much cannabis can a patient carry in Canada?
 - Possession limit of either 30 times the daily quantity of dried cannabis indicated by the health care provider on the medical document, or 150 grams of dried cannabis, whichever is less
- Traveling with cannabis (medical or recreational)
 - Only within Canada
 - Possession limit as above
 - Requires original packaging with patient label intact

Thank you for listening!





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