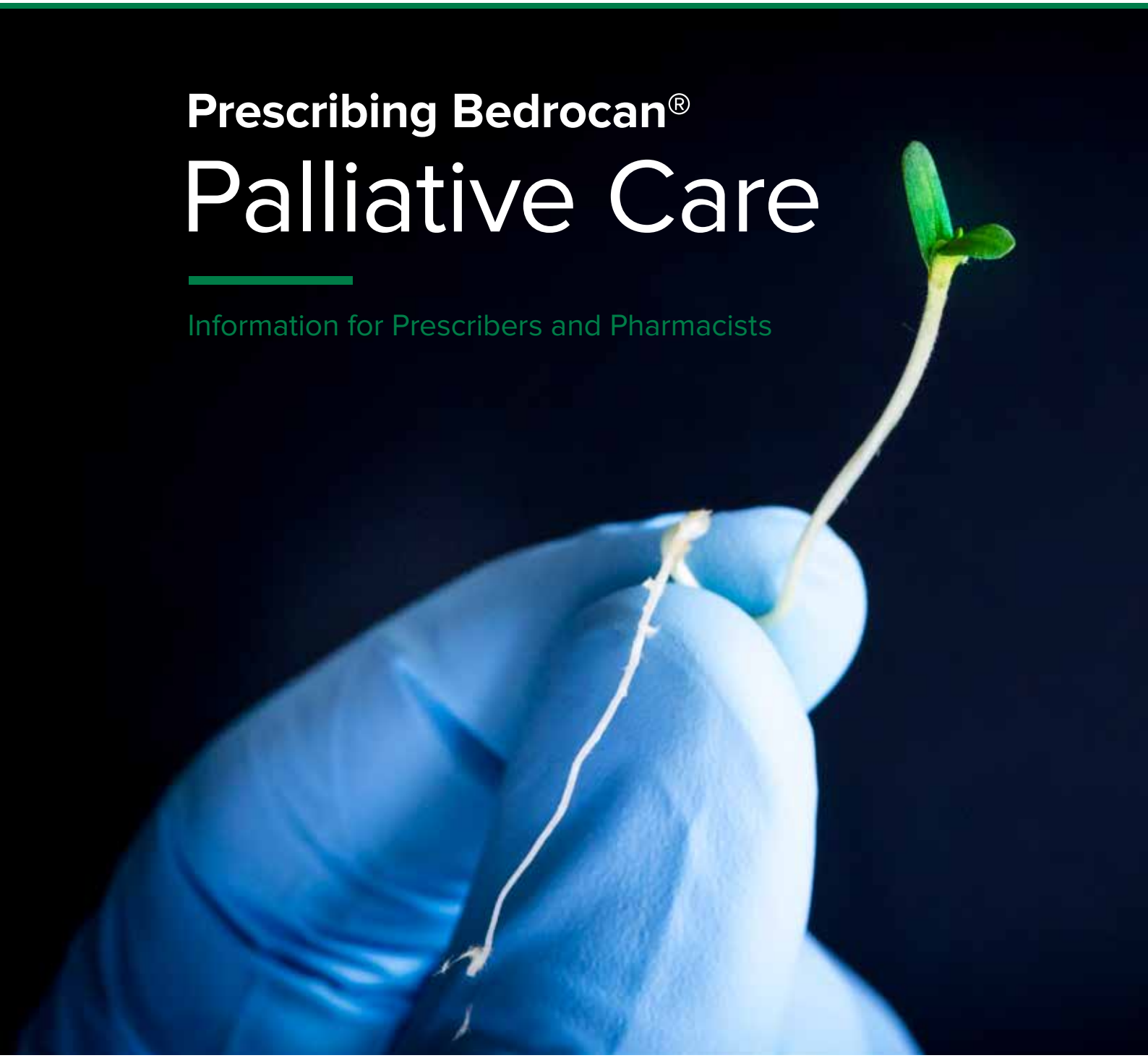
bedrocan®
australia

Prescribing Bedrocan®
Palliative Care

Information for Prescribers and Pharmacists



Content

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Disclaimer
This document is intended for information purposes only, to support decision making by prescribers and pharmacists on the safe and effective use of Bedrocan cannabis flos administered by vaporization. It should not be relied upon as a definitive text. While all efforts have been made to ensure the accuracy and scientific nature of information at the time of its production, Bedrocan makes no representations, implied or otherwise, as to the safety and efficacy of cannabis flos and vaporization technology used to administer it, until such time that reliable clinical data is provided.

Date of Preparation
28 August 2017

Bedrocan Cannabis Flos

Bedrocan is the world's most experienced producer of legal medicinal cannabis. We are the sole supplier to the Dutch Office for Medicinal Cannabis, the government office with a monopoly on supply to Dutch pharmacies, and on its import and export.

GMP-quality assurance

Bedrocan's cannabis flos (the whole, dried flower) is produced to the pharmaceutical-quality standards of GMP (good manufacturing practice). Bedrocan has GMP and ISO quality accreditations. Bedrocan products are reliable because each variety, batch-to-batch, contains a constant composition active ingredients. Using standardised medicinal cannabis products is critical to ensuring the same dose is taken each time. This reproducible chemical profile allows prescribing doctors to monitor dosage and condition progress, and reduces the risk of overdosing and consequently unwanted side effects.

Bedrocan cannabis flos is also free of microbial contaminants (molds, fungi, and bacteria), pesticides, and heavy metals. These qualities make Bedrocan cannabis flos safe for vaporization and inhalation into the lungs, which is especially important for people with weakened immune systems.

Product varieties

Bedrocan currently produces five varieties of medicinal cannabis flos. Each variety has a distinct chemical profile, with a consistent, defined active ingredient composition of delta-9-tetrahydrocannabinol (THC), cannabidiol (CBD), and terpenes (which give cannabis its aroma). These differences result in different effects when used medicinally.

Bedrocan® **THC 22% I CBD <1.0%** **Sativa** **flos**	Introduced in 2003, Bedrocan® is the brand name for the sativa cultivar *Cannabis sativa* L. 'Afina'. *Cannabis sativa* L. 'Afina' is the first cultivar developed and it features 22% THC, with a CBD-level below 1%.
Bedrobinol® **THC 13.5% I CBD <1.0%** **Sativa** **flos**	Introduced in 2005, Bedrobinol® is the brand name for the sativa cultivar *Cannabis sativa* L. 'Ludina'. *Cannabis sativa* L. 'Ludina' is bred in-house by Bedrocan. Its THC-level can be considered medium strength, standardised at 13.5%, with a CBD-level below 1 %.
Bediol® **THC 6.3% I CBD 8%** **Sativa** **granulate**	Introduced in 2007, Bediol® is the brand name for the sativa cultivar *Cannabis sativa* L. 'Elida'. *Cannabis sativa* L. 'Elida' is one of the first cannabis cultivars developed specifically to have a higher CBD content. Bediol® has a balanced ratio of THC 6.3% and CBD 8%.
Bedica® **THC 14% I CBD <1.0%** **Indica** **granulate**	Introduced in 2011, Bedica® is the brand name for the indica cultivar *Cannabis sativa* L. 'Talea'. *Cannabis sativa* L. 'Talea' was developed in response to mounting evidence of a real difference in the effects of sativa and indica varieties. Bedica® contains 14% THC with less than 1% CBD.
Bedrolite® **THC <1.0% I CBD 9%** **Sativa** **granulate**	Introduced in 2014, Bedrolite® is the brand name for the sativa cultivar *Cannabis sativa* L. 'Rensina'. *Cannabis sativa* L. 'Rensina' is a so-called CBD-only product, with less than 1% THC and 9% CBD. The virtual absence of THC means it does not have psychoactive properties.

Pharmacology

Actions

Cannabinoids induce their pharmacological effects by binding to specific cannabinoid receptors (CB), which belong to the superfamily of inhibitory G-protein coupled receptors.[i] So far, two types of cannabinoid receptors (CB1 and CB2) have been identified with certainty. The CB1 receptor is thought to be the most widely expressed G-protein coupled receptor in the brain. However, it is also found in certain peripheral organs and tissues, such as the lungs, liver and kidneys.[ii] CB2 receptors are mainly expressed on certain cells of the immune system, in hematopoietic cells, and in immune-related organs such as the spleen and tonsils.[iii]

These receptors form the human endocannabinoid system which is involved in a host of homeostatic and physiologic functions, including the modulation of pain, appetite, sleep, inflammation, mood, and memory.

The phytocannabinoids THC and CBD are the chief constituents of the cannabis plant. THC acts as a partial agonist at both CB1 and CB2 receptors, which in turn modulate the activity of various physiological systems.[iv] In the case of the CB1 receptor, the modulation of neurotransmitter release, in particular Gamma Amino Butyric Acid (GABA) and glutamate, is most notable.[vvi] CBD has low affinity and a partially antagonistic effect at CB1 and CB2 receptors.[vii] CBD has also been identified to be a serotonin receptor (5-HT1A) agonist.[viii] In addition, it stimulates the vanilloid receptor type 1 (VR1) with a maximum effect similar in efficacy to that of capsaicin.[ix] Furthermore, CBD inhibits the uptake and hydrolysis of the endocannabinoid anandamide, thus increasing its concentration in the tissues where it is produced.[x]

Pharmacokinetics

Absorption

Pulmonary administration of cannabis has been shown to be more effective and reliable than oral or sublingual administration.[xi] THC and CBD are highly lipophilic compounds which are rapidly absorbed by the lungs. Bioavailability of inhaled THC is about 25%.[xii] A dose of 5 milligrams of THC consumed by inhalation reliably produces blood concentrations above the effective level within 6-10 min.[xiii xiv xv]

As a result, cannabis inhalation is a convenient and fast-acting method of administration, allowing self-titration to the desired therapeutic effect. [xvi]

Smoking of cannabis is not recommended because of the presence of the noxious byproducts of pyrolysis. Vaporization offers the advantages of the pulmonary route of administration, while avoiding the respiratory disadvantages of smoking. Although the physical properties of smoking and vaporizing are quite different, both administration forms lead to similar serum concentrations of THC when using the same dose of cannabis. [xvii] Specifically, THC reaches peak plasma levels within minutes after administration. In addition, there is a very low inter-subject variability in THC plasma concentrations with vaporizing, as illustrated by the low standard deviations (see Figure 1).

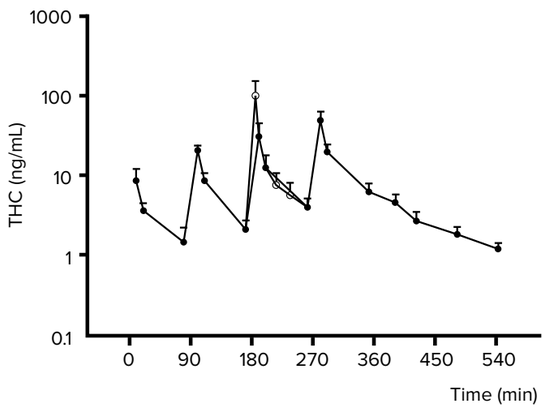


Figure 1 (obtained from Zuurman, et al. 2008). Mean (SD) observed plasma profile of THC: closed circles, common measurement points for all four doses; open circles, extra assessments for third dose. THC administration: 2 mg at T = 0; 4 mg at T = 90; 6 mg at T = 180, 8 mg at T = 270.

Distribution

The pharmacokinetics of THC varies as a function of its route of administration. Absorption of inhaled THC results in a maximum plasma concentration within minutes; psychotropic effects start within seconds to a few minutes, reach a maximum after 15-30 minutes, and taper off within 2-3 hours. In contrast, following oral ingestion, psychotropic effects set in with a delay of 30-90 minutes, reach their maximum after 2-3 hours and last for about 4-12 hours, depending on dose and specific effect. [xviii]

The kinetics of cannabinoids in the body are governed by their lipophilicity and their strong initial binding to serum proteins (approximately 97% for THC). THC is widely distributed, particularly to fatty tissues, but less than 1% of an administered dose reaches the brain, while the spleen and body fat are long-term storage sites. The steady-state volume of distribution for THC averages 3.4 L/kg, which does not change upon co-administration of CBD. [xix]

In humans, plasma THC concentration profiles are similar after pulmonary or intravenous administration, with prompt onset and steady decline. [xx] Pharmacokinetic-pharmacodynamic modeling with plasma THC versus cardiac and psychotropic effects show that after equilibrium is reached, the intensity of effect is proportional to the plasma THC profile. [xxi]

Metabolism

Metabolism of THC occurs mainly in the liver by microsomal hydroxylation, and oxidation catalyzed cytochrome P450 liver enzymes. Besides the liver, other tissues like the heart and lungs are also able to metabolize cannabinoids, albeit to a lesser degree. The two major metabolites of THC are 11-hydroxy-THC (11-OH-THC) and 11-nor-9-carboxy-THC (11-COOHTHC). 11-OH-TH is the most important psychotropic metabolite, being about twice as psychoactive as THC, and it has a similar kinetic profile as the parent molecule. In contrast, 11-COOH-THC has no psychotropic activity. Most of the 11-COOH-THC is finally converted into its glucuronide form, which is the major form of THC excreted into urine. When THC is inhaled through vaporizing, it avoids first-pass metabolism, and conversion to 11-OH-THC and further metabolism takes place much slower. There is no significant difference in metabolism between men and women. [xxii xxiii xxiv]

The metabolism of CBD largely follows the same route as THC, with primary oxidation of C9 to the hydroxy and carboxylic acid moieties and side chain oxidation. Most *in vitro* studies support that CBD does not affect THC pharmacokinetics.[xxv] In addition, CBD does not seem to modulate THC effects through pharmacokinetic mechanisms, except for a slightly slower conversion of 11-COOH-THC to its glucuronide form.[xxvi xxvii]

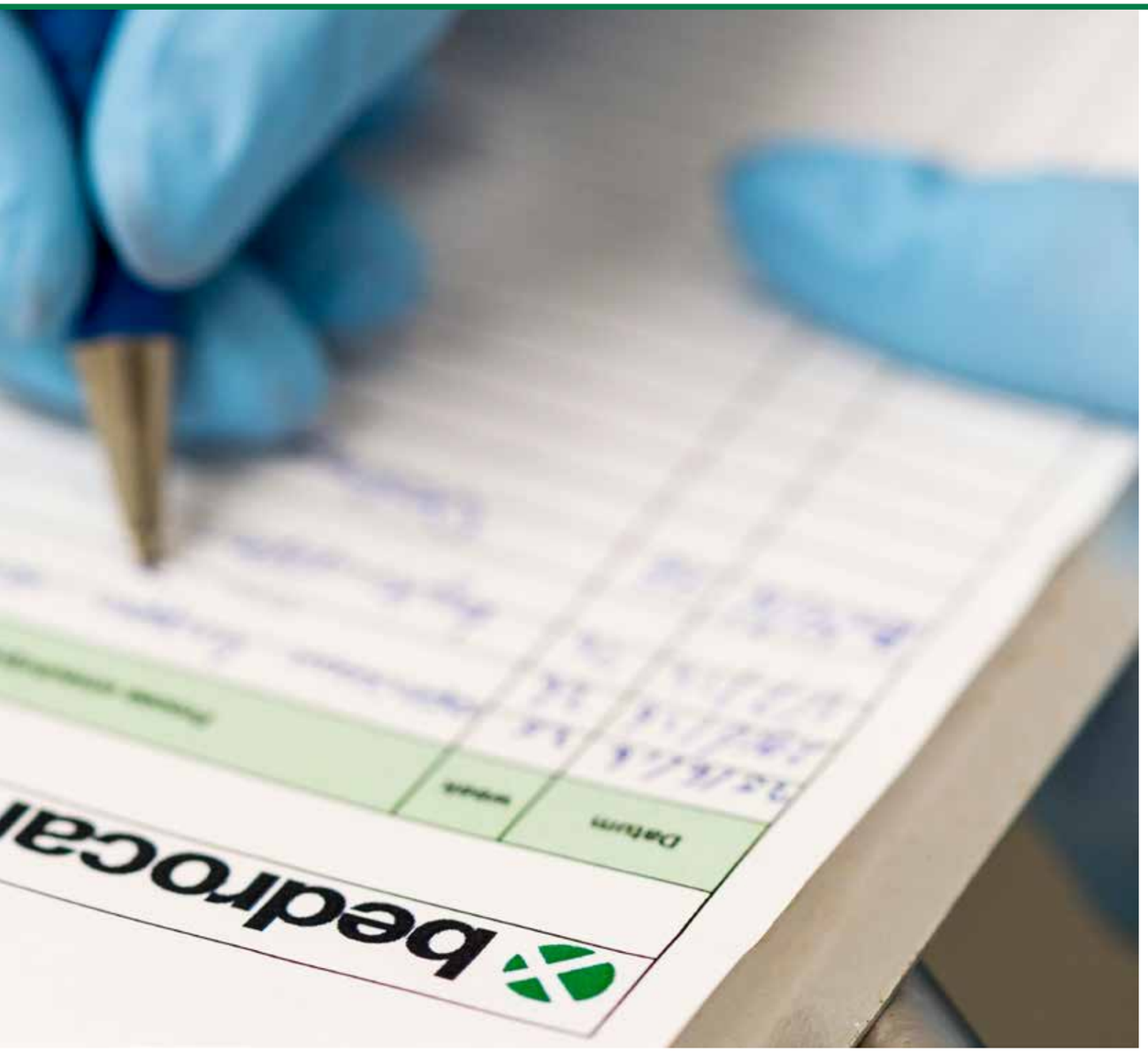
Elimination

Metabolism is the major route for the elimination of THC from the body. The elimination is biphasic; there is a rapid distribution phase (initial half-life about 4 hours), followed by a terminal half-life of around 25 to 30 hours for THC and 11-OH-THC. Plasma half-life for 11-COOH-THC may be even as long as 25-75 hours. The slow elimination of cannabinoids and their metabolites is due to the slow rediffusion from body fat and other tissues into the blood. Body storage of THC increases with increasing frequency and duration of use.

The elimination of THC and its many metabolites (from all routes) occurs via the feces and urine. After inhalation, about 25% of the absorbed dose is excreted in the urine; about 65% is eliminated via feces.[xxviii] Only negligible amounts of THC are excreted unchanged. Less than 5% of an oral dose is recovered unchanged in the feces, and the high lipophilicity of THC, resulting in high tubular re-absorption, is responsible for the low renal excretion of the unchanged drug. Renal clearance of THC metabolites does not seem to be significantly influenced by CBD co-administration.[xxix xxx]

11-COOH-THC is the major metabolite identified in both urine and feces, in its native form and in the form of its glucuronide. Metabolites persist in the urine and feces for several weeks. Following single dose administration, low levels of THC metabolites may be detected for more than 5 weeks in the urine and feces. As for CBD, similarly to THC it is subjected to a significant first-pass effect; however, unlike THC a large proportion is excreted unchanged in the feces.[xxxi]

Uses



Improving quality of life

Palliative care is an approach that improves the quality of life of patients and their families facing the problems associated with life-threatening illness. This is achieved through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual (WHO. Definition of Palliative Care, 2017).

The summary below covers clinical insights for chronic pain, and nausea, vomiting and appetite. Drawing on a history of prescribing and patient use within the Dutch medicinal cannabis program, our **online reference guide** provides insights to the Bedrocan cannabis products prescribed for specific indications in the Netherlands. This may be translated to particular conditions or symptoms treated in the palliative care setting.

Chronic pain

Severe chronic pain seems to be the major reason for which patients use cannabis medicinally. There are many types of pain, and cannabis does not influence each pain type identically. The therapeutic effects of cannabinoids seem to be most pronounced in neuropathic pain – the pain originating from injury or disease that affects the sensory nerves. In contrast, studies measuring the effects on acute pain (e.g. postoperative pain) often show no beneficial effects of cannabis. Most likely, this difference is related to the role endocannabinoids play in both types of pain. However, the mechanism behind this difference is not yet fully understood.

Studies exploring patient therapeutic preferences indicate that for severe pain the majority of side effects from cannabinoids are better tolerated than those from prolonged use of high doses of opioid medications. Chronic neuropathic pain is a common and difficult-to-treat symptom with limited treatment options. As a consequence, even modest therapeutic effects of cannabinoids may be relevant for suffering patients.

Because chronic pain is difficult to treat with any single medicine, cannabinoids have often been studied in combination with other therapeutics, including strong opioids such as morphine. It was found that cannabinoids and opioids work together with a strong combined effect. As a result, the addition of cannabinoids can often result in a lowering of

the opioid dose in a patient's daily drug regimen. Dual therapies have been seen to reduce the unwanted mild to severe side effects of opioids, for example, nausea and vomiting, tolerance, sedation and respiratory depression.

Clinical research overview: Chronic pain

Two literature reviews [xxxii] [xxxiii] over the period 2005 - 2014 identified 22 randomised, double-blind, controlled clinical studies on the effects of cannabinoids for chronic pain, corresponding to a total of 1,842 patients. Most of these studies focused on neuropathic pain using purified cannabinoids or refined cannabis extracts as the study medication.

Out of the 22 clinical studies, 13 of them demonstrated beneficial effects of cannabinoids on chronic pain. However, 5 studies failed to show significant improvement of pain ratings, as compared to placebo or the best available treatment. On the other hand, although 4 other studies also did not show direct positive effects of cannabinoid treatment on pain ratings, they pointed to beneficial secondary effects of the treatment. Specifically, improvement of the quality of life of patients was found to be the most notable benefit.

These results provide limited knowledge to answer the question about the potential of cannabis flos (the whole, dried flower) as a treatment for chronic pain. The reason for that is the fact that most patients in the mentioned studies were administered the cannabinoid preparation Sativex®, instead of herbal cannabis. Consequently, due to the differences in the content between Sativex® and various cannabis flos preparations, which also involve different administration methods, more clinical research involving herbal cannabis is required to better understand its efficacy in the management of chronic pain. Nevertheless, at a minimum cannabinoids have the potential to improve the quality of life of patients.

Nausea, vomiting and appetite

Cannabis can have strong effects on nausea and vomiting resulting from cancer chemotherapy or radiotherapy treatment, hepatitis C, HIV infection or AIDS. Since 1986, synthetic THC (as Marinol®) has been approved by the US Food and Drug Administration (FDA) as an appetite stimulant in the case of anorexia associated with weight loss in patients with HIV/AIDS. Marinol® has also been approved as an antiemetic for cancer patients undergoing chemotherapy. Supporting studies suggest that the addition of THC directly before and after chemotherapy offer more benefit than conventional antiemetic medications alone.

Cannabis has been shown to stimulate appetite, described as a strong desire for foods with high fat or sugar content. For these patients, a high caloric intake may contribute to weight gain and to the absorption of nutrients, often crucial in managing medical conditions such as wasting syndrome.

Although other drugs are available to treat nausea, vomiting, or reduced appetite, the combined effect of cannabis on all these symptoms at once makes it a unique option for contributing to improving a patient's quality of life. For patients suffering from nausea or vomiting, often oral medications are inconvenient. For these patients, administration via inhalation – using a vaporization device – reduces the burden of oral medication and achieves therapeutic levels rapidly.

Clinical research overview: Nausea, vomiting and appetite

The above-mentioned literature reviews over the period 2005 - 2014 identified 7 randomised, double-blind, controlled clinical studies on the effects of cannabinoids for nausea, vomiting and appetite, corresponding to a total of 312 patients. Different cannabinoid administration forms were used in the reported studies, including purified cannabinoids and refined cannabis extracts, as well as inhaled cannabis.

Out of the 7 clinical studies, 5 of them demonstrated beneficial effects of cannabinoids on nausea, vomiting and appetite. However, 2 studies failed to show significant improvement of disease indicators, as compared to placebo or the best available treatment.

Prescribing Bedrocan®

Bedrocan cannabis flos is intended for inhalation by a recommended vaporizer device. Treatment should be initiated and supervised by a doctor with specialist expertise in treating the patient population.

Dosage

Titration

Based upon Dutch patient experience, the dosage varies from patient to patient, and the number and timing of dose administration will vary. On average, patients in the Dutch medicinal cannabis program use 0.7 grams of cannabis flos per day, divided over multiple doses. Patients prescribed cannabis flos to stimulate appetite, reduce nausea, and improve sleep, may use a lower daily dosage than patients prescribed specifically for pain.

A titration period is required to reach a patients' personalised dosage (the optimal dosage). It is suggested that during initial titration, doses are evenly spread out over the day, and according to individual response and tolerability. Patients may gradually increase the dosage, by single dose inhalations, with a minimum 10-15 minute break between inhalations, until they achieve an optimal dosage.

It is important that the dosage is titrated slowly, whichever cannabis flos product is used. Most unwanted side effects may be prevented by following these guidelines:

- **Low dose -** it is better to take several small doses in a day that add up to the required result, than to experiment with one single large dose.
- **Patience -** cannabis may have a different effect on each patient. Wait for the effect (if any) to appear. It's best to use the same (low) dosage for several days, and monitor any effects that may occur.
- **Increase dose slowly -** after a few days the patient can increase the dosage, but slowly. Take a few days after each increase to monitor progress.

Patients should be advised that it might take between one to two weeks to find their personalised dosage (the optimal dosage) that gives the greatest medicinal effects with minimum side effects.

Dosing is self-limiting. Individual response and side effects will establish an upper-limit for the dosing of this medicine. During the titration period undesirable, usually mild, side effects can occur. Side effects typically resolve after a few days use. If side effects are unpleasant for the patient, doctors should recommend maintaining or reducing the dosage. If unacceptable adverse reactions such as dizziness or other intoxication-type reactions occur then dosage should be reduced and potentially tapered off or ceased.

Some of the psychological effects of the psychoactive cannabinoid THC experienced by patients include dysphoria and mild anxiety. These can be minimised through preparation, explanation and reassurance given before the start of the treatment. This should especially be considered when administered in the palliative setting, and with the elderly.

Dosage maintenance

Following the titration period, patients are advised to maintain their personalised dosage (the optimal dosage).

Titration upwards or downwards may be appropriate if there are any changes in the severity of the patient's condition, changes in their concurrent medication, or if side effects or adverse reactions develop which are unacceptable for patient safety and comfort.

Regimen review

The patient's response to the inhalation of cannabis flos should be regularly reviewed. If a clinically significant improvement is not seen during the dosage maintenance period, then prescribers should consider ceasing treatment. The value of long-term treatment should be re-evaluated periodically.

While the risk of dependence is low at clinical dosages, in long-term therapy a patient's potential for such symptoms should be evaluated. Prescribing doctors should monitor patients for signs of excessive use, misuse, and dependence. Patients with a personal or familial history of substance dependence are at higher risk of than other patients.

General guidance – planning treatment

Prescribers should consider generating a treatment protocol, which includes the following:

The starting dose	Guidance for the starting dose, and for titration up and down (how dosage adjustments would be made). Prescribers should keep in mind that the pharmacologic effects of inhaled cannabis are dose related. Systemic absorption from the inhalation of cannabis flos vapour and the intensity of the effect due to this route of administration is often greater than an equal dose taken orally.
Reducing or tailing-off current treatments	Consider the procedure for reducing or tailing-off current and/or concurrent medicines and treatments that maybe considered, or become redundant for the treatment of the specified condition(s) if cannabis flos is found to be efficacious.
Assessment of efficacy	Consider suitable diagnostic and measurement technique(s) to assess the safety and efficacy of the recommended regimen. Consider a plan to reassess the condition and determine overtime if the desired effect has been obtained and maintained.
Risk mitigation	Consider: • The nature and/or describe the effect of (potential) drug-drug interactions within the overall proposed regimen. Prescribers should consider how interactions with drugs and concomitant disease will be identified and treated. • Poly-pharmacy within the context of the inclusion of an additional drug to a patient's regimen and with the overall proposed treatment plan. • The potential risks with prescribing in the elderly.
Cessation of treatment	Consider a plan to stop or modify treatment at a particular dosage if no significant effect has been seen, or if intolerable side effects have occurred, or if dependence or diversion for misuse has been identified.
Returns protocol	Confirm a protocol for returning unwanted or unused cannabis flos, and if required and necessary the vaporizer device.

Administration - Vaporization

Administration by vaporization requires pulmonary inhalation. It is recommended that only patients with the capacity to produce a minimum airflow of 10 L/min be considered for this mode of administration.

Vaporizer devices

Quality vaporizer devices offer patients an effective, safe, and easy to use delivery system for cannabis flos.[xxxiv xxxv] The inhaled vapour contains THC, CBD, and terpenes[1] in consistent, measurable quantities.

Pharmaceutical-quality cannabis flos

For vaporization to be truly effective, the cannabis product used must be of pharmaceutical quality. Fully standardised cannabis flos assures dosage composition, repeatability and the ability for patient and prescriber to effectively adjust dose by titration.

Cannabis flos must be shown to be free of contaminants such as microbes, pesticides and heavy metals, qualities that make the vapour safer for inhalation into the lungs. Bedrocan cannabis flos is presented in pharmacy containers which have been gamma irradiated to eliminate potential bio-burden.

Administration route

The most efficient administration route of medicinal cannabis is by inhalation. Indeed, administration by inhalation is a rapid way to induce measurable serum levels of cannabinoids.[xxxvi] The vapour is quickly absorbed by the lungs, permitting patients to effectively titrate to optimise their dose based upon symptom severity, tolerability and avoidance of side effects.
The rapid onset of effects of inhaled cannabinoids allows easier titration of dose, while standardised cannabis products enable patients to administer an exact dose.[vi]

	Administration Absorption via the lungs reduces total daily intake.
	Dose type Cannabis flos is used in granulated (ground up) form. A vapour of cannabinoids and terpenes is inhaled.
	Onset First effects can be noticed within minutes.
	Duration Typically between 2 -4 hours.
	Safety Harmful compounds are virtually absent.

[1] Terpenes are a major component of *Cannabis sativa* L. Responsible for the plant's aroma, terpenes may also act synergistically with the cannabinoids.[x]

Patient perspectives

The importance of vaporization is underlined in patient use surveys. The majority of survey respondents report higher satisfaction (approval) scores with the inhalation route. In general, cannabis flos received higher scores than other products containing isolated cannabinoids.[xxxvii xxx viii] The presence of non-THC constituents, including anti-inflammatory terpenes that protect the lungs from irritation, are present in the cannabis flos vapour.[xxxix] Vaporizing administers the full range of therapeutic compounds present in the cannabis plant.

Vaporizing vs smoking

The advantage of vaporizing over smoking is obvious with regard to irritation and respiratory complication resulting from smoking. The use of a quality vaporizer device avoids the respiratory disadvantages of smoking, by virtually eliminating exposure to toxic compounds linked with cannabis smoke.[xl]

A quality vaporizer device, compared to smoking, dramatically lowers concentrations of toxic compounds such as carbon monoxide, ammonia and polyaromatic carbohydrates (PACs). Compared to smoking, higher therapeutic levels of THC and consistent, reproducible THC extraction and delivery is possible.[xli xlii]

Vaporization devices

Dispensing

Hands should always be thoroughly washed before dispensing cannabis flos or granulate. Dispensing cannabis flos or granulate into the vaporizing basket should be done using a thoroughly clean dispensing spatula. Physical contact with the cannabis flos or granulate should be avoided to reduce microbial burden and to maintain product sterility.

When dispensed, the cannabis flos or granulate dose will be contained within the basket which sits within the vaporizer device.

Extraction

Before an initial administration, patients should be given instructions on safe and effective inhalation, as follows:

- Ask the patient to try inhaling through the inhalation mouthpiece a few times;
- Be sure that the patient is able to take deep breaths through the inhalation mouthpiece;
- Instruct patients to exhale completely before inhalation.

Upon administration, patients should be instructed to inhale 5 seconds of vapour from the device and hold their breath for 5 seconds after each inhalation. Inhalations must be constant and soft. If the inhalation is too fast or too strong, the subject may start coughing, and may feel burning in their lips or palate.

Patients, if they are able to swallow, should be provided water, if requested. This may help with throat irritation and minimise coughing, and therefore loss of the administered dose.

Disposal of spent material

The extraction of the active compound, THC, is never totally complete. Current vaporizer technology is capable of up to 90% extraction. Therefore, spent material should be disposed of safely and responsibly. The entire contents of the basket can be placed into a container filled with chlorine solution (standard thin bleach at approximately 5% chlorine concentration).

This will degrade THC and make the plant material absent of THC, thus making the material not suitable for misuse. This method has been approved by the Dutch Office of Medicinal Cannabis as a proper way of disposing of cannabis and preventing illegal distribution.

Second-hand exposure

Reducing second-hand exposure to exhaled vapour is important. Administration by vaporization should occur in a well-ventilated room, and use around children should be strictly avoided.

Cleaning and maintenance

See attached documentation for detailed information on cleaning and maintenance of the vaporizer.

Cleaning of the vaporizer basket and inhalation mouthpiece can be achieved using a wash bottle with pure ethanol solution (which should be kept out of reach of children). Ethanol will dissolve the leftover cannabinoids. The basket can be reused an unlimited number of times after careful cleaning. The inhalation mouthpiece can be reused around 20-30 times, after becoming opaque. After this time, the inhalation mouthpiece should be replaced.

Safety measures

To assure safety, the vaporizer is recommended to be used as follows:

- Use and store the device in a cool, dry place.
- Never cover/store the device when it is turned on.
- Place device and dock on a flat, smooth surface away from heat and humidity sources.
- Never exhale into the vaporizer; this causes overheating, battery explosion and dirt accumulation in the inner chamber.
- Never clean the vaporizer when it is connected to the battery or charging dock or when it is hot (the vaporizer should not need cleaning).
- Use the cleaning tools provided.
- Never leave the vaporizer running without supervision.
- Keep out of reach of children.

Warnings and Precautions

Potential medicine interactions

CYP450 interactions with cannabinoids

The constituents of cannabis flos, THC and CBD, are metabolised by the cytochrome P450 enzymes. When taken together with other medicines metabolised by the cytochrome P450 enzyme system, there may be the potential for drug-drug interactions.

Other potential drug-drug interactions with cannabinoids[xliii]

Care should be taken when prescribing cannabis flos (as THC) with hypnotics, sedatives and medicines with sedating effects. Specifically, THC may interact with alcohol, affecting response time, co-ordination, and concentration. THC reinforces the sedating effects of other psychotropic substances (e.g. benzodiazepines), and interacts with compounds that act on the heart and circulation (beta-blockers, diuretics, adrenaline, stimulants). THC may enhance the antiepileptic action of benzodiazepines and the antiemetic effect of phenothiazines. Cannabinoids appear to enhance the analgesia induced by opiates. While, the cyclooxygenase inhibitors indomethacin, acetylsalicylic acid, and different non-steroidal anti-inflammatory drugs counteract THC effects.

Potential side effects

Overview

In general, patients seem to tolerate medicinal cannabis well: the possible side effects are transient (last a short time), mostly benign, and resolve as tolerance builds. When properly administered, medicinal cannabis does not have identified toxic effects on patient health. Unwanted side effects mainly occur after the intake of large doses, or when medicinal cannabis is used in combination with other substances that increase its effects (e.g. alcohol or particular medications).

Research regarding expected adverse effects of cannabis use in a therapeutic context is limited. Consequently, a significant amount of data on this issue is derived from studies investigating recreational cannabis use, which implies caution in formulating conclusions regarding medicinal use. Specifically, the amount of cannabis used, the methods of delivery and the existence of comorbidities significantly differ between the recreational and medicinal cannabis user populations. As a result, different adverse effects might be expected.

Side effects

A review of the effects of the medicinal use of cannabinoids indicated that the most frequent categories of adverse effects relate to respiratory, gastrointestinal, and nervous system disruptions.

The common acute side effects of high doses of cannabis occur quickly after consumption, including:

- dry mouth
- redness of the eyes
- heightened appetite (which may be desirable)
- mild euphoria
- reduction of alertness of the user, especially in the few hours directly after consumption
- increased heart-rate
- lowering of blood pressure and dizziness.

In general, all side effects are transient. They should slowly decrease and then disappear within a few hours.

Preventing side effects

Most unwanted side effects from the administration of medicinal cannabis may be prevented by adopting the following guidelines:

- start with a low dose – it is better to take several small doses in a day
- be patient and wait for the effects to appear
- use the same (low) dosage for several days, and monitor any side effects that may occur
- increase the dosage slowly – take plenty of time to increase until the optimal dosage is found
- be in a safe environment when initiating cannabis-based therapies (especially during the first administrations)
- have a trusted person around for support during the initiation period.

Preventing getting ‘high’

When using larger doses of medicinal cannabis, a user may experience a ‘high’ – a mild intoxication, best described as a mild euphoria or an experience of distorted reality (which may culminate in a mild anxiety). The main component of cannabis, the cannabinoid THC, is responsible for these psychoactive effects.

The Bedrocan cannabis variety Bediol has a higher CBD content, which has been shown to be capable of suppressing the psychoactive effects of THC.

Most often, the feeling of being ‘high’ is experienced as a mild euphoria – the feeling of being happy and energised. As time passes, this changes to feelings of being content and relaxation. Some individuals may experience mild impairment of short-term memory, an increase in heart rate, uncontrolled laughter, and changes in the awareness of their surroundings (colours, sounds). With large doses, mild visual and auditory hallucinations may occur. In a recreational setting, these symptoms are mostly mild and appreciated.

For inexperienced users or after the consumption of high doses these symptoms can result in acute feelings of anxiety. In these cases, most often, it is sufficient to sit or lay down in a calm and comfortable location, preferably with someone familiar to talk to. If there is an experience of an unwanted ‘high’, this can usually be prevented by consuming lower doses, or by administering the dose slowly over a longer period.

Prescribing for the elderly

Elderly patients are more sensitive to the neurological, psychoactive and posturalhypotensive effects of cannabinoids. This is especially applicable to elderly patients who are prone to falls and those with dementia. Therefore, dose selection for an elderly patient should be conducted with caution, starting at the low end of the dosing range. This low dose also reflects the greater frequency of decreased hepatic, renal and cardiac function and the incidence of concomitant disease, an increased body fat content, and the probability of poly-pharmacy in this population.

A special warning

Patients with a hereditary risk of psychosis or other psychiatric conditions (e.g. schizophrenia or depression), and patients with cardiac/coronary conditions should avoid the use of cannabis and cannabinoids, as they may potentiate these conditions. Specifically, the potential of cannabinoids to indirectly affect dopamine levels in the brain may be negatively impact the functioning of psychosis patients. In addition, the potential of cannabis to induce hypertension, tachycardia, catecholamine release, and vascular constriction poses a risk to patients with cardiac/coronary conditions.

Risks

Just like any other medicine, medicinal cannabis is not without risks. The most important risk factors are briefly described below.

Psychosis

On rare occasions, cannabis use can induce a state of psychosis in individuals with a genetic predisposition. As a result, patients with a (family) history of psychotic disorders, particularly schizophrenia and bipolar disorder, should be under careful psychiatric monitoring when using medicinal cannabis. Moreover, a short, acute psychotic like episode (anxiety and depression) is possible in the case of non-predisposed individuals, especially when very high doses of THC is taken.

Occasionally, new scientific reports appear on the effects of cannabis on risk of psychosis. However, a direct link between cannabis and psychosis has not yet been established. The discourse surrounds the question: does cannabis induce psychosis in otherwise totally healthy individuals, or does pre-existing genetic vulnerability for psychosis result in adverse outcomes from cannabis use?

Recent scientific studies into this matter suggest a small proportion of the population has genetic predispositions that increase the risk of developing chronic psychotic symptoms when using cannabis (as a medicine or otherwise).

Heart disease

Cannabinoids can have a strong, but temporary, effect on heart rate and blood pressure. Patients with a history of heart disease or receiving medication for heart disease should avoid their use, or only use cannabis under careful supervision by a medical doctor.

Pregnancy and lactation

The use of medicinal cannabis during pregnancy is likely to affect the development of the fetus. Because certain components of cannabis - including THC - are excreted in breast milk, the use of medicinal cannabis is also not advised while breastfeeding. Therefore the introduction or continuation of reliable contraception is advised for the duration of and several months after treatment.

Liver disease

After cannabis administration, the liver is the main organ involved in chemically altering the cannabinoids as part of its function to process and excrete external substances by the body (metabolism).

The effects of cannabis may therefore be significantly different in patients with a liver disease. Therefore, these patients should be monitored during initiation to ensure the dosage taken does not exceed the livers metabolic capacity.

Addiction

The evidence suggests that the risk of developing an addiction to cannabis when taken as a medicine is minimal. The recommended dose for medicinal use is often lower than that of a recreational user, and a medical professional should always be involved in medicating and monitoring the patient.

Patients should take particular care, however, if they have prior problematic substance use. High doses of medicinal cannabis, taken over long periods, may lead to dose escalation and misuse. The abrupt cessation (quitting) may then cause withdrawal symptoms, such as mild forms of restlessness, irritability, insomnia, vivid dreams, and decreased appetite.

Overdosing

The consumption of medicinal cannabis has not been shown to lead to life threatening adverse events, even at very high doses. However, an overdose of cannabis (THC) can result in a range of adverse effects, with high variability in tolerance between subjects. The most common adverse effect of overdosing a single dose of THC is anxiety, which, in some cases, may lead to mild acute panic attacks. In addition, increased heart rate and changes in blood pressure may occur.

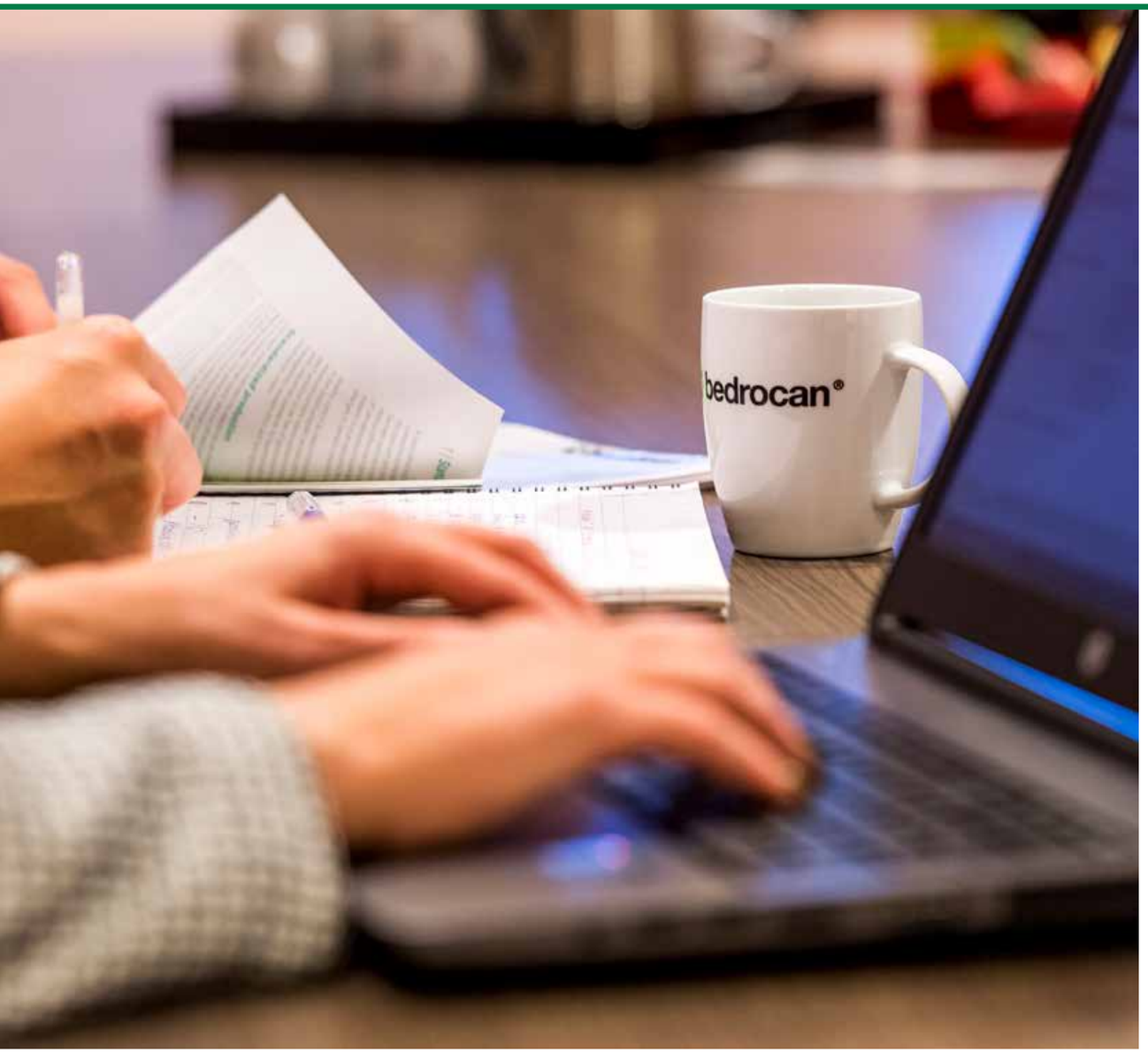
Specifically, it is possible that a THC overdose will result in acute hypotension and/or tachycardia. In rare cases, nausea and vomiting and diarrhoea have been observed. That aside, impaired executive function and motor control may lead to feelings of confusion, depersonalisation, loss of control, or even helplessness. Also reddened eyes and a dry mouth may be experienced as very unpleasant to some individuals. Most adverse effects will spontaneously resolve, usually within a few hours, when serum levels of THC fall.

There are suggestions that in a small number of cases THC is capable of precipitating psychosis, involving delusions and hallucinations. If these side effects occur, they seem to be rare, because they most likely require very high doses of THC administered over a prolonged period of time, or a pre-existing genetic vulnerability. However, there is enough reason to be cautious and communicate these risks in a fair and balanced way.

Driving and operating machinery

Cannabis at therapeutic doses may produce undesirable effects such as dizziness and drowsiness which may impair judgement and performance. In addition, psychomotor functioning may be negatively affected even at a low THC dose and patients might be more attracted by intrapersonal stimuli (“self”) instead of orienting attention to driving performance. Moreover, cannabis has been shown to decrease the ability to monitor and correct erroneous behavior. Consequently, patients should not drive, operate machinery or engage in any potentially hazardous activity under the influence of cannabis.

Pharmacovigilance



What is pharmacovigilance?

Pharmacovigilance is the collecting, monitoring, researching, assessing and evaluating of information from healthcare providers and patients on the adverse effects of medications.

An awareness of the potential for adverse effects, the diagnosis of such events, and their reporting, is essential during the course of a patient's treatment with medicinal cannabis.

Bedrocan relies on the patients and their careers, and healthcare professionals to report problems with medicines and the accompanying vaporization device. Bedrocan can then investigate reports, identify the specific cause, and determine any necessary regulatory action to resolve the problem.

Adverse events

There are a number of known medicine interactions and potential side effects related to the medicinal use of cannabis. These are discussed above in the section *Warnings and Precautions*. Patients and prescribing doctors should familiarise themselves with these and reduce or mitigate medicine interactions and the potential for side effects in the patients' daily regimen.

Reporting adverse events

Patients should inform their doctors about adverse events from their medication, and that related to the accompanying vaporization device. Prescribing doctors should make reports of adverse events at **https://bedrocan.com/au/products-services/healthcare/reporting-adverse-effects/**

Or to Novachem by:
email: bedrocan@novachem.com.au
phone: 1800 NOVACHEM (1800 668 224) or +61 3 8415 1255
fax: +61 3 8625 0088

Diversion and misuse

Medicinal cannabis is considered to be a desirable and divertible pharmaceutical due to the inherent nature of its active substances. Medicinal cannabis, like other controlled drug substances, requires the same oversight and considerations by prescribing doctors and pharmacists to limit diversion and misuse.

While patients in the palliative care setting have an intensive and structured doctor-patient relationship, alongside well planned and monitored daily medicine regimen, there remains a risk of medicine diversion for misuse.

Storage and Dispensing

Storage - pharmacy

Room temperature

Cannabis flos or granulate, packaged in 5 gram official pharmacy packaging and irradiated, may be guaranteed up to 1 year at 25°C and 60% RH.

Storage - patient

Safe storage

It is evident that no pharmacy will have a secure freezer for storage. Cannabis flos or granulate should be stored in the official pharmacy packaging in a safe and secure place, away from heat and direct sunlight, and out of reach of children.

Special precautions for disposal

Cannabis flos and granulate containing greater than 2% delta-9- tetrahydrocannabinol (THC) is a Schedule 8 (S8) Controlled Drug substance of the Poisons Standard (the Schedule of Medicines and Poisons), and requires a prescription. Any waste material should be disposed of in accordance with local requirements and suggested methods detailed in the above section Prescribing: Vaporization devices. Unused material should be taken back to the dispensing pharmacy.

Dispensing

Cannabis flos must be handled by a certified pharmacy and dispensed by a qualified pharmacist. Patients should receive their dose based on a medical doctor's prescription in conjunction with relevant SAS/AP documentation from the TGA.

Presentation

Classification

Cannabis flos is an unapproved medicine in Australia.

Cannabis flos and granulate containing greater than 2% delta-9- tetrahydrocannabinol (THC) is a Schedule 8 (S8) Controlled Drug substance of the Australian Schedule of Medicines and Poisons (Poisons Standard), and requires a prescription.

Cannabis flos and granulate containing cannabidiol (CBD) and 2% or less of other cannabinoids found in cannabis (as THC) is a Schedule 4 (S4) Prescription Only Medicine of the Poisons Standard.

Nature and contents of container

Contents: Cannabis flos or granulate as *Cannabis sativa* L.
Pack Size: 5 grams of cannabis flos or equivalent granulate.
Container type: Polyethylene container and cap, the contents of which are sterilised via gamma irradiation to eliminate potential bioburden.

Accessing Medicinal Cannabis

Unapproved medicines

While there are medicinal cannabis products regulated as medicines in Australia, most products are not currently registered on the Australian Register of Therapeutic Goods (ARTG). These therefore must be supplied in Australia using alternative pathways while evidence to support registration is gathered through clinical trials.

SAS and AP Schemes

The TGA administer the Special Access Scheme (SAS) and Authorised Prescriber Scheme which allow eligible medical practitioners to apply for the importation and supply of medicinal cannabis products that are not registered on the ARTG:

- Special Access Scheme **www.tga.gov.au/form/special-access-scheme**
- Authorised Prescribers **www.tga.gov.au/form/authorised-prescribers**

Step-by-step guidance

The TGA have put together a useful resource which summarises the requirements for an Australian registered medical practitioner to access medicinal cannabis products. Included also is information to determine state/territory regulatory requirements.
See: **www.tga.gov.au/access-medicinal-cannabis-products-steps-using-access-schemes**

Bedrocan Australia

Bedrocan cannabis flos are able to be ordered by wholesale suppliers and pharmacies in Australia through Novachem. The products currently available through Bedrocan are listed on Novachem's website: **www.novachem.com.au/page/bedrocan-medicinal-cannabis-products**

Particulars

Name and address

Bedrocan products are imported and distributed in Australia by Novachem Pty Ltd
25 Crissane Road, Heidelberg West Vic 3081, Australia
email: bedrocan@novachem.com.au
phone: +61 3 8415 1255

Bedrocan Australia Pty Ltd is a subsidiary of Bedrocan International **www.bedrocan.com**

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History of Bedrocan

Founders Tjalling Erkelens and Freerk Bruining - 1984

At Bedrocan we have been growing cannabis for more than two decades. We are the sole supplier of medicinal cannabis to the Office for Medicinal Cannabis (OMC), the government office with a monopoly on supply to Dutch pharmacies, and on its import and export.

With quality guaranteed through oversight by the OMC, patients, their prescribers and governments across numerous countries have trust in our products. This trust is reinforced by Bedrocan's reliability, integrity and commitment. And that commitment does not stop with standardised, pharmaceutical quality products.

Our heritage has its roots in the disciplined agricultural traditions of northern Netherlands. In 1984, Bedrocan began specialising in the indoor cultivation of plants under standardised and controlled conditions growing chicory, culinary herbs, potted plants and other crops. Building on this expertise, in the 1990s, we turned our focus to using the most advanced agricultural technology to develop something new: standardised, quality controlled whole-flower cannabis.

Bedrocan started as a family business, and we maintain those roots as we continue to grow. Today, Bedrocan is the world's most experienced producer of legal medicinal cannabis.

Our medicinal cannabis has played an important role in numerous research projects. In fact, Bedrocan cannabis has been used to establish reference standards for major analytical tests used to identify the presence of cannabinoids in test samples.

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