

# Prescriber Update

## Clinical research review



### Quality Assurance

Bedrocan®

22.0% THC | < 1.0% CBD

Bedrocan® has a consistent composition of active ingredient, batch-to-batch, dose-to-dose.

Standardisation allows prescribers to better monitor dosing, condition progress, and minimise side effects.

A high-quality vaporizer device is an effective inhalation delivery system. It makes it possible to titrate to an optimal dosage (e.g. Storz & Bickel).



### Active ingredient profile

22.0% Δ-9-THC (Δ-9-Tetrahydrocannabinol)

< 1.0% CBD (Cannabidiol)

The terpene profile of Bedrocan® *Cannabis sativa* L. 'Afina':

- terpinolene
- myrcene
- cis-ocimene
- beta-2-pinene
- R-limonene
- BCP
- gamma-elemene
- alpha-2-pinene
- borneol



## Clinical research review

**Over the last 20 years a number of clinical studies and scientific research projects have been performed on Bedrocan®. This clinical research review is a summary of the most current.**

### Bedrocan®

Bedrocan® is the brand name of the variety *Cannabis sativa* L. 'Afina'. Administered by inhalation it may have positive effects on subjective pain intensity in a variety of pain-related medical conditions, with most research focussing on neuropathic pain. Further randomised controlled trials are planned and needed to demonstrate safety and efficacy.

### Pain – opioid-sparing treatment option

Bedrocan® may be used as part of an opioid-sparing strategy in the treatment of pain. In this study of pain clinic patients, 78.5% were prescribed an oral dose of Bedrocan®, with most patients receiving a prescription for 12 months (range 8-21 months). At study initiation, 20% of the cohort were prescribed high doses of opioids (> 90 mg morphine equivalent/day). A high benzodiazepine prevalence was also observed. After 6 months of cannabinoid therapy, a significant increase in the number of patients not receiving opioid medications was identified (from 32.1% to 55.4%). However, a decrease in anticonvulsant, antidepressant, and benzodiazepine medications did not occur.

Study reference: Nunnari et al. (2022). European Review for Medical and Pharmacological Sciences.

### Pain – no additional respiratory depression

Respiratory depression is a common side effect of strong opioids. The co-administration of inhaled Bedrocan® (100 mg cut flos) has no effect on ventilatory control after pre-treatment with placebo or oxycodone (20 mg) in a randomised controlled crossover trial in healthy individuals.



The inhaled  $\Delta$ -9-THC dose, taken at 1.5 and 4.5 hours post the oral oxycodone dose, did not enhance opioid induced respiratory depression. Oxycodone itself reduced iso-hypercapnic ventilation (VE55) by 30% from baseline. The second cannabis inhalation had no effect on VE55. The co-administration of oxycodone and  $\Delta$ -9-THC increased the degree of sedation by up to 30% and mild intoxication by up to 10%, and decreased energy state by up to 30% and the state of alertness by up to 40%.

Study reference: Van Dam et al. (2023). *British Journal of Anaesthesia*.

### Fibromyalgia – an alternative treatment

Bedrocan® may represent an alternative analgesic for patients diagnosed with fibromyalgia but who do not respond well to conventional treatments (i.e. tramadol, amitriptyline, duloxetine, pregabalin).

This retrospective study showed this cohort of pain clinic patients responded well to Bedrocan® 200 mg/day cut flos. A reduction in pain intensity was found at 1, 3, and 12 months of treatment. Significant improvements were observed in the Numerical Rating Scale (NRS), Oswestry Disability Index (ODI), Hospital Anxiety and Depression Scale, Widespread Pain Index (WPI), Severity Score (SyS) at 1 month; in NRS, ODI, and WPI at 3 months; and in NRS, ODI, and SyS at 12 months.

Most patients treated with Bedrocan® continued their therapy. Stopping therapy was due to non-serious, transient side effects such as confusion and dizziness. An appropriate titration period would help reduce the incidence of these side effects, and improve medicine efficacy and treatment compliance.

Study reference: Mazza. (2021). *Journal of Cannabis Research*.

### Avoiding side effects

Often CBD (cannabidiol), a non-intoxicating cannabinoid, is prescribed to attenuate the psychotropic side effects of  $\Delta$ -9-THC. A recent study, however, shows CBD does not influence any of the cognitive impairments or psychological symptoms.<sup>1,2</sup> Neither does CBD attenuate any of the other acute effects of  $\Delta$ -9-THC, including behaviour, subjective experiences, and cognition.

Additionally, co-administration of CBD had no influence on Tmax, metabolites OH-THC or COOH-THC, or to total systemic exposure (AUC).<sup>3</sup> A recent study demonstrated that CBD after a 450mg oral dose of CBD can increase the acute effects of  $\Delta$ -9-THC, likely explained by CBD inhibiting cytochrome P450-mediated metabolism of THC.<sup>4</sup>

Study references:

- 1 Chester et al. (2022). *Journal of Cannabis and Cannabinoid Research*.
- 2 Lawn et al. (2022). *Addiction*.
- 3 Englund et al. (2022). *Journal of Neuropsychopharmacology*.
- 4 Gorbenko et al (2024). *Clinical Pharmacology & Therapeutics*.

### Bedrocan's Clinical Research Unit

The complete understanding of the safety and efficacy of cannabis medicines is confounded by variation in study design, the specific indications studied, the dose and administration form.

Bedrocan's Clinical Research Unit is located in the Netherlands. Our clinical researchers are currently working on two critical projects to further elucidate the safety and efficacy of Bedrocan®:

- A randomised, double-blind, controlled trial to assess acute subjective, behavioural, cognitive, cardiovascular, and pharmacokinetic effects after inhalation of Bedrocan®. The study will also focus on any potential differences between females and males.  
(Study Reference - SEDICAN).
- A retrospective database review of the prescribing patterns and clinical effects of medicinal cannabis in the Netherlands, in collaboration with the leading Dutch pharmacies Transvaal, Clinical Cannabis Care, and MYCB1.  
(Study Reference - MEDICAN).



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