Prescribing Bedrocan®

Treatment planning

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.

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

Treatment planning

Bedrocan® has been available on special access prescription in the Netherlands since 2003, Italy in 2007, Germany in 2008, and Australia in 2017. Administered by inhalation, Bedrocan® may have positive effects on subjective pain intensity in a variety of pain-related medical conditions. Further randomised controlled trials are needed to demonstrate safety and efficacy.

Administration

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

Dosing

The available clinical data indicate the intensity of physiological and psychological effects is proportional to the Δ-9-THC plasma concentration.

Start with a low dose. A titration period is required to reach an optimal daily dosage (an individual dose x the frequency of dosing).

A maximum Δ-9-THC dose may vary according to patient response. Dosing is self-limiting, with side effects establishing an upper dose limit. Side effects are nuanced, time and dose dependent, and are typically transitory in nature.

Side effects

Most side effects are the result of a large dose, but may be influenced by dosing frequency, comorbidities, and concomitant medicine interactions. Common acute side effects may include dry mouth, redness of the eyes, heightened appetite, mild euphoria (intoxication), reduction of alertness, increased heart rate, lowering of blood pressure and dizziness.

Total available dose

100 mg of Bedrocan® cut flos equates to 22.0 mg Δ-9-THC. This is the maximum Δ-9-THC available for inhalation, and depends upon the vaporiser device quality, a patient's duration of an inhalation, breath depth and hold.

On average half of the 'standard' loaded dose is delivered from a vaporizer device. Over a third of the inhaled dose may be exhaled. Inter- and intra-patient variability in plasma concentrations of Δ-9-THC is therefore possible.

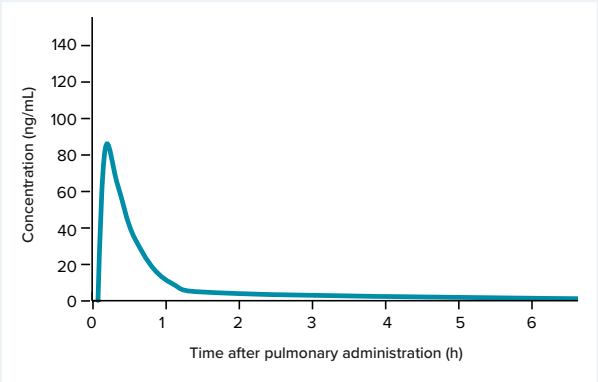
Absorption

Bioavailability of inhaled Δ-9-THC is approximately 40%.

Δ-9-THC is highly lipophilic and rapidly absorbed in the lung. Peak plasma concentrations are typically reached 3-10 minutes after inhalation.

Physiological and psychological effects start within seconds to a few minutes, reaching a maximum after 10-30 minutes, and then taper off within 1-3 hours.

Figure: Approximate plasma concentrations (82 ng/ml) after pulmonary administration of Bedrocan® (22.0 mg Δ-9-THC)



Metabolism

Many medicines are metabolised in the liver by cytochrome P450 enzymes which may result in medicine-medicine interactions. There are several important interactions with Δ-9-THC which can alter medicine pharmacokinetics or pharmacodynamics. It is important to review all medications used by the patient beforehand.

Dosing Bedrocan®

100 mg cut flos contains:

- THC: 22.0 mg
- CBD: < 1.0 mg

Pk parameters of inhaled vapour:

- Cmax
  - THC: 82 ng/ml
  - CBD: < 0.2 ng/ml
- Tmax
  - 5 min

Study reference: Van de Donk et al (2019). Pain.

Warnings and precautions

Δ-9-THC is contraindicated in the context of pregnancy. Extra caution is advised in patients with a history of mental illness, substance dependence, cardiovascular disease, renal or hepatic disease, adolescents, and the elderly and frail.

Bedrocan® should not be prescribed to patients taking high doses of opioids (> 90 mg morphine equivalent per day) or benzodiazepines due to compounding sedative effects.

Δ-9-THC interferes with cognitive and psychomotor functions can be deleterious for a complex task like driving or operating machinery.

Preparing a treatment plan

- Prescribing should be guided by the pharmacokinetic properties of an inhaled medicine.
- A titration period is required to reach the optimal daily dosage for all patients. Start with a low total daily dosage, spread out over the day in several small doses.
- The influence of patient comorbidities and potential medicine interactions need to be considered in dosing decisions.
- Bedrocan® should not be prescribed to patients taking high doses of opioids or benzodiazepines. Consider tapering down high doses of these medicines when prescribing Δ-9-THC.
- Patients should be advised that the treatment may be discontinued if a net benefit has not been obtained.

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Recent clinical research on Bedrocan®

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Supporting studies

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