Prescribing Bedrocan® forte

Treatment planning

Quality Assurance

Bedrocan® forte *Cannabis sativa* L. 'Afina'
25.0% THC | < 1.0% CBD

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

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

Bedrocan® forte is chemically and genetically identical to the standard Bedrocan® chemovar, and complies with the European Pharmacopoeia Cannabis flos monograph (3208).

Active ingredient profile

25.0% Δ^9-THC (Δ^9-Tetrahydrocannabinol)
< 1.0% CBD (Cannabidiol)

Treatment planning

Bedrocan® forte (25% Δ^9-THC) is a high-strength, pharmaceutical-grade cannabis flos. It is derived from the same *Cannabis sativa* L. 'Afina' chemovar (variety) as the standard Bedrocan® chemovar (22% Δ^9-THC), which has been available since 2003.

Administered via inhalation, Bedrocan® forte is expected to exhibit a pharmacological profile comparable to Bedrocan®. With a Δ^9-THC content of 25%, a more cautious dose titration is warranted to account for the higher strength.

Bedrocan® forte may support symptomatic management of chronic and severe conditions, including use in oncology, palliative care, and pain settings. Additional randomised controlled trials are needed to confirm safety and efficacy.

Administration

Bedrocan® forte is administered via inhalation using a vaporizer device (e.g. Storz & Bickel vaporizers). A high-quality vaporizer device makes it possible to titrate to an optimal daily dosage.

Treatment initiation

Treatment should be initiated at a low dose and titrated gradually to achieve the optimal therapeutic effect while minimising the risk of overdose. Individualised titration is essential to balance efficacy and tolerability.

Bedrocan® forte is not recommended for initiation in THC-naïve individuals.

Patients should be advised that the treatment may be discontinued if a net benefit has not been obtained.

Transitioning from Bedrocan® standard

Transitioning from Bedrocan® (22% Δ^9-THC) to Bedrocan® forte (25% Δ^9-THC) requires adjustment of dose and dosing frequency to reflect the higher Δ^9-THC content. Patient education on titration protocols is required to minimise potential side effects.

Dosing

Start with a low dose. A titration period is required to reach an optimal daily dosage (an individual dose x the frequency of dosing). Typically, the daily dosage should be spread out over the day in several small doses.

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

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.

The influence of patient comorbidities and potential medication interactions needs to be considered in dosing decisions.

Total available dose

100 mg of Bedrocan® cut flos equates to 25.0 mg Δ^9-THC. This is the maximum Δ^9-THC available for inhalation, and depends upon the vaporizer device quality, a patient's duration of 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 lungs. Peak plasma concentrations are typically reached 3-10 minutes after inhalation, with mean Cmax increasing proportionally with the administered dose. Δ^9-THC exhibits nonlinear pharmacodynamic properties, with a dose-dependent increase in the incidence and severity of side effects, alongside interindividual variability in tolerability.

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.

Metabolism

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

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.

Monitor for Δ^9-THC-dose-related side effects, such as dizziness, sedation, and psychotropic reactions. Regular cognitive assessments may be appropriate for patients on long-term treatment.

Ongoing review of therapeutic goals and dose optimisation is essential to maintain efficacy and minimise harm with this higher-strength formulation.

Warnings and precautions

Δ^9-THC is absolutely contraindicated in cannabinoid hypersensitivity, pregnancy, and breastfeeding. Avoid in children/adolescents unless specialist-led, as long-term risks remain uncertain. Exercise heightened caution in patients with a history of psychiatric illness, substance use disorder, cardiovascular, renal, or hepatic impairment, as well as in older adults and frail individuals.

Δ^9-THC is primarily metabolised via CYP2C9, CYP3A4 and CYP2C19. Co-administration with other CYP450 substrates, inhibitors, or inducers of CYP450 enzymes may alter plasma concentrations and clinical effect. Clinical significance varies and should be assessed case by case.

Bedrocan® forte is not recommended for patients using high-dose opioids (>90 mg morphine equivalent/day) or benzodiazepines due to additive sedative effects. If co-prescribed, initiate at low doses and monitor for adverse neurocognitive effects. Consider tapering concurrent CNS depressants where appropriate.

Δ^9-THC may impair cognitive and psychomotor function. Patients should be advised not to drive or operate hazardous machinery while under its influence.

References

- Bilbao, A., & Spanagel, R. "Medical cannabinoids: A pharmacology-based systematic review and meta-analysis for all relevant medical indications ." *BMC Medicine* (2022): 20:259. https://bmcmedicine.biomedcentral.com/articles/10.1186/s12916-022-02459-1.
- Cremer-Schaeffer, P., Hennig, B., Schmidt-Wolf., G et al. "Prescriptions of cannabinoid drugs, 2019–2022—a comparison of data from the German Federal Institute for Drugs and Medical Devices and the BARMER health insurance fund." *Deutsches Ärzteblatt* (2023): 120(11).
- Grotenhermen, F. "Pharmacokinetics and pharmacodynamics of cannabinoids." *Clin Pharmacokinet* (2003): 42(4):327–360.
- Hennig, B., Schmidt-Wolf, G., Cristinziani, A., et al. "High-Cost and High-Dose Prescriptions of Cannabis-Based Medicines - A Comparison of Data From BARMER and the German Federal Institute for Drugs and Medical Devices (BfArM)." *Dtsch Arztebl Int.* (2023): 120(47):813–814.
- Leen, N., Kowal, M., Batalla, A., Bossong, M. "The effects of standardized cannabis products in healthy volunteers and patients: a systematic literature review." *Frontiers in Pharmacology* (2024).
- Lucas, J., Galettis, P., Schneider, J. "The pharmacokinetics and the pharmacodynamics of cannabinoids." *British Journal of Clinical Pharmacology* (2018): 84(11):2477–2482.
- Mazza, M. "Medical cannabis for the treatment of fibromyalgia syndrome: a retrospective, open-label case series." *Journal of Cannabis Research* (2021): 3(4):2-18.
- Van Dam, C., van der Schrier, R., van Velzen, M., et al. "Inhaled Δ^9-tetrahydrocannabinol does not enhance oxycodone-induced respiratory depression: a randomised controlled trial in healthy volunteers." *British Journal of Anaesthesia* (2023).
- Van de Donk, T., Niesters, M., Kowal, M., Olofsen, E., Dahan, A., van Velzen, M. "An experimental randomized study on the analgesic effects of pharmaceutical-grade cannabis in chronic pain patients with fibromyalgia." *Pain* (2019): 160(4):860–869.

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