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Disclaimer and copyright

Product information

Dosage form
Oromucosal solution, drops

Container size and type
30 mL amber glass bottle with syringe adaptor and child resistant, tamper-evident screw cap.

Active ingredients
- Δ^9-tetrahydrocannabinol (THC): 25.0 mg/mL
- Cannabidiol (CBD): <1.0 mg/mL

Excipients
Medium chain triglycerides (MCT)

Administration syringe

Formulation	Content	Content per per 0.1 mL
THC only	THC 25.0 mg/mL	2.5 mg THC
Balanced	THC 10.0 mg/mL+ CBD 10.0 mg/mL	1.0 mg THC 1.0 mg CBD
Balanced	THC 25.0 mg/mL CBD 25.0 mg/mL	2.5 mg THC 2.5 mg CBD

Storage
- Store below 25 °C
- Store upright in the original package
- Protect from heat and moisture
- After first opening, use within 120 days
- Keep the bottle tightly closed

Shelf life
Unopened: 24 months
Opened: 120 days from date of opening.

Treatment planning

Bedromed drops is a pharmaceutical grade cannabinoid formulation derived from Bedrocan's standardised *Cannabis sativa* L. chemovars. It is formulated for oromucosal administration in a medium chain triglyceride (MCT) solution. MCT serves as a stable, well-tolerated lipophilic carrier suited to cannabinoid solubility, supporting consistent dosing and individualised titration.

Bedromed drops is available under special access provisions as an unapproved medicine for oromucosal (sublingual) administration.

Published clinical studies on THC-containing medicines has explored potential effects on subjective pain intensity across several chronic pain conditions, including neuropathic pain, multiple sclerosis, rheumatoid arthritis, fibromyalgia, and cancer-related painStudies have also examined potential effects on the symptomatic management of moderate to severe spasticity in adults with multiple sclerosis who have not responded adequately to other anti-spasticity medications. [1, 2, 5, 10, 14, 17, 18, 19, 20, 22]

Randomised controlled trials are required to establish the safety and efficacy of Bedromed drops for these indications.

Treatment should be initiated and supervised by a physician experienced in the relevant patient population.

Administration

Bedromed drops is administered sublingually (under the tongue). A portion of the dose is absorbed through the oral mucosa, with the remainder absorbed via the gastrointestinal tract following swallowing. As is typical for this route of administration, the onset of effect is gradual and should be considered during titration.

The syringe administers between 0.1 mL and 1.0 mL of solution. The container should be shaken before use. Cannabinoid effects are dose dependent and subject to considerable interindividual variability. Absorption and clinical response are influenced by factors such as mucosal permeability, salivary flow, swallowing, and recent food intake.

Consistency in administration technique is critical: holding the dose sublingually for 60–90 seconds, spreading it thinly across the mucosa rather than pooling, and avoiding drinking for 10–15 minutes afterwards, all enhance mucosal uptake.

Because food intake can significantly affect bioavailability, patients should be advised to maintain a consistent administration routine - either always with food or always in a fasted state - to minimise variability in absorption and clinical effect.

For some patients, particularly those who are frail, elderly, or have limited mobility, using a syringe can be challenging. Difficulty in placing the dose correctly inside the cheek may increase the risk of under or over dosing. Clear instructions on proper syringe technique are essential to minimise errors. Patients must be cautioned not to confuse a 0.1 mL dose with a 1.0 mL dose, as illustrated below.

Dosing

Initiate treatment at a low dose and titrate gradually. Individualised titration is essential to optimise the balance between efficacy and tolerability (see table 1: Titration schedule).

A conservative dosing protocol is recommended for the following populations: Elderly or frail patients; Children and adolescents; Individuals with a current or past history of mental illness; Patients with cardiovascular disease; Patients with a history of seizures; Patients with renal or hepatic impairment; Patients receiving multiple medicines, particularly those known to interact with cannabinoids. [10]

Patients should be advised that identifying an optimal dose and total daily dose may require up to two weeks. Transient side effects (e.g. dizziness) may occur during this titration period.

Titration schedule

A titration period is required to reach the optimal single dose and total daily dosage (see table 1: Titration schedule). The number and timing of doses should be tailored to the indication and adjusted according to individual response and tolerability.

Titration principles: Start low, go slow

Initiate treatment with a small dose rather than a large one. Maintain a low total daily dosage during the initiation phase to minimise side effects.

Incremental increases

If symptom relief is insufficient after a single dose, cautiously increase the total daily dosage. Adjustments should be made at appropriate intervals to allow assessment of both efficacy and tolerability.

Dose adjustments

Upward or downward titration may be appropriate in response to:

- Changes in symptom severity
- Introduction or discontinuation of concomitant medications
- Emergence of side effects

Optimal daily dosage

Dose increases should be slow and incremental, continuing until the patient achieves adequate symptom relief with acceptable tolerability. This titration process identifies the patient-specific optimal daily dosage.

Clinical guidance suggests that dosages above 20 mg THC/day are associated with a higher likelihood of side effects and may contribute to tolerance without additional therapeutic benefit. Dosages above 40 mg THC/day are generally not recommended and should only be considered in exceptional circumstances under specialist supervision.

Lower total daily dosages may be appropriate for some patients depending on individual sensitivity, comorbidities, and concomitant medications.

Ongoing clinical monitoring is essential throughout initiation and maintenance to assess response, tolerability, and dose-related side effects.

Dosing schedule considerations

During initiation, the evening dose should be administered close to the patient's usual bedtime to minimise interference with daily activities and to monitor for sedative effects. When a morning dose is introduced, it should be taken between waking and midday, allowing sufficient time to assess daytime tolerability and impact on general functioning.

Titration schedules

These titration schedules are an example of a titration approach described in the literature and does not constitute a recommended regimen.

Dosing must be individualised according to indication, response, and tolerability. Dose increases should be slow and incremental,

continuing until the patient achieves adequate symptom relief with acceptable tolerability.

Clinical monitoring is required throughout initiation and maintenance to assess response, tolerability, and dose-related effects.

The tables illustrate how side effect risk increases with higher total daily THC exposure.

Note: Titration schedule is illustrative only, not a recommended regimen, dosing subject to indication, individual response, tolerability, clinical monitoring required.

- Each 0.1 mL of solution contains (2.5 mg THC)
- A low dose is defined as 0.1 mL (2.5 mg THC)
- A high dose is defined as 1.0 mL (25 mg THC)

Clinical oversight is required for all dose adjustments.

Table 1: Example titration schedule – formulation THC 25.0 mg/mL + <1.0mg/mL CBD

Per 0.1 mL: 2.5 mg THC + <0.1 mg CBD
Maximum total daily dosage: 1.6 mL = 40 mg THC

Morning dose (mL)	Evening dose (mL)	Total daily dose (mL)	Total THC dose (mg)
0	0.1	0.1	2.5
0.1	0.1	0.2	5.0
0.1	0.2	0.3	7.5
0.2	0.2	0.4	10.0
0.2	0.3	0.5	12.5
0.3	0.3	0.6	15.0
0.3	0.4	0.7	17.5
0.4	0.4	0.8	20.0

Dosages above 20mg THC/day are associated with a higher likelihood of side effects.

Morning dose (mL)	Evening dose (mL)	Total daily dose (mL)	Total THC dose (mg)
0.4	0.5	0.9	22.5
0.5	0.5	1.0	25.0
0.5	0.6	1.1	27.5
0.6	0.6	1.2	30.0
0.7	0.7	1.4	35.0
0.8	0.8	1.6	40.0

Dosages above 40 mg THC/day are generally not recommended.

Table 2: Example titration schedule – formulation 10 mg/mL THC + 10 mg/mL CBD

Per 0.1 mL: 1.0 mg THC + 1.0 mg CBD
Maximum total daily dosage: 4.0 mL = 40 mg THC + 40 mg CBD

Morning dose (mL)	Evening dose (mL)	Total daily dose (mL)	Total THC dose (mg)	Total CBD dose (mg)
0.0	0.25	0.25	2.5	2.5
0.25	0.25	0.50	5.0	5.0
0.25	0.50	0.75	7.5	7.5
0.50	0.50	1.00	10.0	10.0
0.50	0.75	1.25	12.5	12.5
0.75	0.75	1.50	15.0	15.0
0.75	1.00	1.75	17.5	17.5
1.00	1.00	2.00	20.0	20.0

Dosages above 20mg THC/day are associated with a higher likelihood of side effects.

Morning dose (mL)	Evening dose (mL)	Total daily dose (mL)	Total THC dose (mg)	Total CBD dose (mg)
1.00	1.25	2.25	22.5	22.5
1.25	1.25	2.50	25.0	25.0
1.25	1.50	2.75	27.5	27.5
1.50	1.50	3.00	30.0	30.0
1.75	1.75	3.50	35.0	35.0
2.00	2.00	4.00	40.0	40.0

Dosages above 40 mg THC/day are generally not recommended.

Table 3: Example titration schedule – formulation 25 mg/mL THC + 25 mg/mL CBD

Per 0.1 mL: 2.5 mg THC + 2.5 mg CBD
Maximum total daily dosage: 1.6 mL = 40 mg THC + 40 mg CBD

Morning dose (mL)	Evening dose (mL)	Total daily dose (mL)	Total THC dose (mg)	Total CBD dose (mg)
0.0	0.1	0.1	2.5	2.5
0.1	0.1	0.2	5.0	5.0
0.1	0.2	0.3	7.5	7.5
0.2	0.2	0.4	10.0	10.0
0.2	0.3	0.5	12.5	12.5
0.3	0.3	0.6	15.0	15.0
0.3	0.4	0.7	17.5	17.5
0.4	0.4	0.8	20.0	20.0

Dosages above 20mg THC/day are associated with a higher likelihood of side effects.

Morning dose (mL)	Evening dose (mL)	Total daily dose (mL)	Total THC dose (mg)	Total CBD dose (mg)
0.4	0.5	0.9	22.5	22.5
0.5	0.5	1.0	25.0	25.0
0.5	0.6	1.1	27.5	27.5
0.6	0.6	1.2	30.0	30.0
0.7	0.7	1.4	35.0	35.0
0.8	0.8	1.6	40.0	40.0

Dosages above 40 mg THC/day are generally not recommended.

Treatment maintenance and evaluation

Following the titration period, the established dosing schedule should be maintained, provided the treatment remains effective and well-tolerated.

A formal review of the patient's response is recommended after four weeks of continuous treatment. If no clinically meaningful improvement is observed during this period, or if side effects become intolerable or adverse effects arise, treatment should be discontinued. Clinical judgement should guide decisions regarding continuation, modification, or cessation of therapy, with consideration given to patient-reported outcomes and tolerability.

Warnings and precautions

Prescribers should be aware that both absolute and relative contraindications apply to the use of THC-containing products. These include, but are not limited to, pregnancy, hypersensitivity to cannabinoids, and certain psychiatric, cardiovascular, hepatic, and neurological conditions. In addition, clinically significant medication interactions may occur. Cannabinoids can alter the pharmacokinetics and pharmacodynamics of co-administered medicines, particularly those metabolised via the cytochrome P450 enzyme system, potentially leading to reduced efficacy or increased toxicity. [10]

Hypersensitivity reactions

A history of hypersensitivity to cannabinoids constitutes an absolute contraindication.

Pregnancy and lactation

Bedromed drops is contraindicated during pregnancy, anticipated pregnancy, and lactation. Cannabinoid exposure during gestation is associated with subtle but enduring neurodevelopmental risks, including potential effects on cognition and psychological health. Due to the potential for cannabinoid transfer into breast milk and associated risks to the infant, breastfeeding should be avoided during treatment.

Paediatric use

There is a well-documented association between early, frequent, and heavy recreational use of THC during adolescence and adverse cognitive and psychiatric outcomes in adulthood.
Although causality remains unconfirmed, Bedromed drops should only be used in children and adolescents under exceptional circumstances, and treatment should be initiated and supervised by a paediatric specialist.

Psychiatric disorders and substance dependence

There A current or a history of mental health disorders, particularly psychosis, substance misuse, or dependence, are relative contraindications. Bedromed drops containing THC in these populations is a relative contraindication and should be managed in collaboration with a qualified mental health or addiction specialist.

Seizure disorders and severe cardiac conditions

Seizures and severe cardiac disorders are relative contraindications. A neurologist should be consulted in patients with epilepsy or a seizure history. A cardiologist should be consulted for patients with cardiovascular disease.

Driving and operating machinery

THC may impair cognitive and psychomotor performance, including the ability to drive or operate machinery. Patients should be cautioned about driving and performing hazardous tasks while undergoing treatment with THC-containing medicines, particularly during initiation, dose titration, or following any dose increase. Patients must also comply with local legal restrictions regarding driving after the use of THC-containing products.

Alcohol use

Alcohol may elevate plasma concentrations of THC, potentially intensifying its sedative and psychomotor effects. Co-administration should be avoided.

Concomitant use with opioids or benzodiazepines

Bedromed drops containing THC should not be prescribed to patients on high-dose opioids or benzodiazepines due to the risk of additive sedation and cognitive impairment.

- Consider tapering down high-dose opioids (>90 mg morphine equivalent/day) or benzodiazepines prior to initiation;
- Start at the lowest effective dose and titrate cautiously;
- Monitor closely for changes in memory, mood, or functional status;
- If adverse effects occur, immediate dose reduction or cessation is required.

Medicine interactions

Bedromed drops may interact with other medications that patients are taking concurrently. THC exhibits several clinically relevant interactions that can alter the pharmacokinetics or pharmacodynamics of co-administered medicines. These interactions may lead to reduced efficacy or increased toxicity.

Many medicines, including cannabinoids, are metabolised via the hepatic cytochrome P450 enzyme (CYP450) system. THC is primarily metabolised by CYP2C9, CYP3A4, and CYP2C19. Therefore, medications that act as inducers or inhibitors of these enzymes can significantly influence cannabinoid plasma concentrations. Additionally, THC is known to inhibit CYP1A1, CYP1A2, and CYP1B1, which may further contribute to interaction risk. [4, 23, 25]

A comprehensive medication review should be conducted prior to initiating Bedromed drops, with particular attention to agents metabolised via CYP450 pathways.

Table 4: Known and potential interactions with cannabinoids

Medication class	Clinical rationale
Anti-infective medicines	Inhibitors of CYP3A4, such as the antifungal agent ketoconazole, may significantly increase Cmax and AUC of THC. Antibacterials can be both inducers (rifampicin, which lowers cannabinoid levels) and inhibitors (clarithromycin, which raises cannabinoid levels). Requires careful monitoring and dose adjustment. Triazole antifungals (itraconazole, fluconazole, ketoconazole) are broad-spectrum CYP inhibitors (especially CYP3A4). They can increase THC levels in the blood. Protease Inhibitors (ritonavir) are CYP3A4 inhibitors. Co-administration impairs cannabinoid clearance, leading to higher systemic concentrations and toxicity risk.
Anticoagulants	Warfarin is a substrate of CYP2C9. THC may inhibit CYP2C9, which can lead to elevated warfarin levels and increased risk of bleeding.
Anti-convulsants	Additive CNS effects (e.g. dizziness, confusion, sedation, somnolence) may occur when THC is taken concomitantly with CNS depressants. Phenytoin, phenobarbital, and carbamazepine are known CYP inducers.
Anti-psychotics & anti-depressants	Co-administration of THC may increase plasma concentrations of SSRIs, tricyclic antidepressants, antipsychotics. Additive CNS effects (e.g. dizziness, confusion, sedation, somnolence) may occur when THC is taken concomitantly with CNS depressants.
Cardiovascular medicines	Additive cardiac effects (e.g. hypotension, hypertension, syncope, tachycardia) may occur when THC is taken concomitantly with medicines which affect the cardiovascular system. Many beta-blockers, antiarrhythmics, and calcium channel blockers are CYP substrates (CYP2D6, CYP3A4). Interactions can alter blood pressure control or cardiac rhythm. Most statins are CYP3A4 substrates, which can increase statin levels, raising the risk of muscle toxicity.
Opioids & sedatives	Additive CNS effects resulting in cognitive impairment (e.g. dizziness, confusion, sedation, somnolence) may occur when THC is taken concomitantly with CNS depressants. Opioids and benzodiazepines are CYP3A4 or CYP2D6 substrates, potentially leading to increased sedation, respiratory depression, and adverse events.

Undesirable effects and overdose

Bedromed drops may cause undesirable effects.

A side effect is a documented therapeutic or adverse response that occurs secondary to the intended treatment effect. In adult patients, most side effects are mild and transient in nature and resolve within a few hours. The severity and frequency of side effects can vary depending on the dose and individual patient characteristics. Importantly, side effects should not be mistaken

for effects of concomitant medication interactions.
Adverse effects - harmful and unintended reactions - typically necessitate clinical intervention or treatment discontinuation. [2,14]

Table 5: Common and known side effects of THC

The following side effects are listed in approximate order of decreasing frequency or clinical relevance, based on available literature and pharmacovigilance data. Most side effects are dose dependent.

Physiological effects:
Dry mouth
Ocular redness
Increased appetite
Dizziness
Euphoria
Reduced attention
Memory deficits
Nausea and vomiting
Sleep-related effects:
Impaired long-term sleep quality and disruptions in sleep cycles
Psychological effects:
Anxiety
Depression and suicidal behaviour
Psychosis and schizophrenia
Cardiovascular effects:
Arrhythmias (tachycardia or bradycardia)

Mechanism of action

Cannabinoids induce their pharmacological effects by binding to specific cannabinoid-binding receptors (CB1 and CB2), which belong to the human endocannabinoid system (ECS). THC has the capability to bind and activate both CB-receptor types, and administration of THC may lead to a variety of effects on the physiological systems that are normally regulated by endocannabinoids. [14]

Pharmacokinetic properties

Absorption

Cannabinoids are highly lipophilic compounds, rapidly absorbed via the sublingual mucosa. There is a high degree of interindividual variability, influenced by factors such as mucosal integrity, salivary flow, swallowing behaviour and food intake. [11; 24]

The fraction absorbed via the sublingually mucosa rapidly enters the systemic circulation, yielding a fast onset of action and a higher, dose-dependent Cmax. However, the volume swallowed introduces significant variability and increases the formation of the psychotropic metabolite 11-OH-THC. While overall exposure is generally dose proportional, it remains highly variable, influenced by the lyophilic vehicle (MCT oil), the patients administration technique, and individual metabolic differences.

Table 6: Approximate pharmacokinetics of Bedromed drops

Dose mg of THC	**Cmax** ng/mL (mean)	**Tmax** hours (mean)
0.1 mL (2.5 mg THC)	**1–3 ng/mL**	**1.0–2.5 hours**
	Predominantly sublingual absorption. Limited swallowed dose Fastest onset. Tmax is driven by the rate of mucosal uptake, resulting in a quicker peak. [16, 24]	
0.5 mL (12.5 mg THC)	**3–8 ng/mL**	**1.2–3.0 hours**
	Larger volume increases the portion swallowed, contributing to a delayed Tmax due to swallowed fraction and hepatic metabolism of THC to 11-OH-THC. [6,12,24]	
1.0 mL (25 mg THC)	**6–15 ng/mL**	**1.5 – 3.5 hours**
	Highest dose results in the highest Cmax but with the widest variability due to swallowed fraction and hepatic metabolism of THC to 11-OH-THC. [3,22] *Peak can be delayed by food.* [24]	

Note: The pharmacokinetic information presented is approximate, derived from emerging data and extrapolation from related cannabinoid formulations. It does not constitute definitive clinical findings and should not be used as the sole basis for therapeutic decisions. The data are provided only to support prescriber awareness.

Distribution

Following sublingual administration, systemic plasma concentrations of THC are generally lower than those achieved via inhalation of an equivalent dose.

Both cannabinoids are highly lipophilic and may accumulate in adipose tissue, from which they can be slowly released over time at sub-therapeutic plasma concentrations. This redistribution may contribute to prolonged detection windows and delayed pharmacodynamic effects in some patients.

Metabolism

THC is primarily metabolised hepatically via cytochrome P450 isoenzymes CYP2C9, CYP3A4, and CYP2C19.

THC is metabolised to 11-hydroxy-THC (11-OH-THC), its primary active metabolite with psychotropic properties, estimated to be approximately twice as potent as THC. This metabolite contributes significantly to the overall pharmacological and psychoactive profile of THC. THC is further oxidised to 11-nor-9-carboxy-THC (11-COOH-THC), a secondary metabolite that is pharmacologically inactive but commonly used as a biomarker of THC exposure. It is and is subsequently excreted.

Elimination

Cannabinoid elimination follows a biphasic pattern, with an initial half-life of approximately four hours and a terminal elimination half-life ranging from 24 to 36 hours.
The extended terminal phase is due to a gradual release of cannabinoids from adipose tissue, resulting in low-level plasma concentrations over time. Metabolites are excreted via renal and biliary pathways. [12; 13]

Medicine Status

Bedromed drops is an unapproved medicine on prescription supplied via special access pathways. Formulations containing THC are classified as controlled substances under applicable legislation.