

4. Possible side effects of Bedromed drops

Like all medicines, this medicine can cause side effects, although not everybody gets them. Most side effects are mild and transient (short-lived) and usually resolve within a few hours. Side effects are often dose-dependent and may vary depending on the THC dose.

Possible side effects

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)

If you experience any side effects that are **severe, intolerable, or concerning**, stop using Bedromed drops and contact your doctor immediately.

Reporting side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects, you help improve the safety monitoring of this medicine.

5. How to store Bedromed drops

Storage

- Store below 25 °C;
- Store upright in the original package;
- Protect from heat and moisture;
- Keep the bottle tightly closed.

Shelf life

- **Unopened:** 24 months;
- **Opened:** 120 days from date of opening.

6. Contents of the pack and other information

What Bedromed drops contains

The active ingredients are Δ^9 -tetrahydrocannabinol (THC) and cannabidiol (CBD). The other ingredients (excipients) are medium-chain triglycerides (MCTs).

What Bedromed drops looks like and contents of the pack

Bedromed is an oromucosal solution. It comes in a 30 mL amber glass bottle with a child-safe, tamper-proof cap. The bottle has a special plug (adaptor) in the neck to make it easy to use the syringe. Each pack contains a measuring syringe that allows you to take a dose between 0.1 mL and 1.0 mL.

Bedromed drops Oromucosal solution, drops

Patient Information

Active ingredients:

- Δ^9 -Tetrahydrocannabinol (THC) and/or;
- Cannabidiol (CBD).

Formulations:

THC 25.0 mg/mL and CBD <1.0 mg/mL
THC 10.0 mg/mL and CBD 10.0 mg/mL
THC 25.0 mg/mL and CBD 25.0 mg/mL

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again;
- If you have any further questions, ask your doctor or pharmacist;
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours;
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. **See section 4.**

1. What Bedromed drops is and what it is used for

What Bedromed drops contains

Bedromed is an oromucosal solution, which means it is absorbed through the lining of your mouth (under the tongue). It contains THC as the active ingredient at a strength of 10.0 mg to 25.0 mg per mL, depending on the prescribed formulation.

What Bedromed drops is used for

Bedromed drops is an unapproved medicine available under special access provisions. This means it is still being studied in formal clinical trials, but your doctor has prescribed it for you under special access rules to help with:

- Reductions in subjective pain intensity in adults with chronic pain (e.g., neuropathic pain, multiple sclerosis, rheumatoid arthritis, fibromyalgia, cancer-related pain);
- Symptomatic relief of moderate to severe spasticity in adult patients with multiple sclerosis who have not responded adequately to other anti-spasticity medications.

2. What you need to know before you take Bedromed drops

Do not take Bedromed drops

- If you are pregnant or are planning to become pregnant;
- If you are breastfeeding;
- If you are allergic to cannabinoids (THC or CBD) or any of the other ingredients of this medicine (**listed in section 6**).

Warnings and precautions

Talk to your doctor or pharmacist before using Bedromed drops, especially if you have:

- A history of mental illness, particularly psychosis, substance misuse, or dependence;

Disclaimer and copyright

This product has not been granted marketing authorisation. This means it has not undergone the full regulatory assessment, including of its safety and effectiveness. This leaflet provides the most current information available to support discussions between you and your doctor and pharmacist. Because this product is unapproved, its use is governed by the laws and regulations of your country. Your doctor is responsible for determining whether its use is appropriate for your individual clinical needs.



- Cardiovascular disease (heart problems);
- A history of seizures or epilepsy;
- Renal (kidney) or hepatic (liver) impairment;
- If you are elderly or frail;
- If you are taking multiple other medicines (see below).

Children and adolescents

Bedromed drops should only be used in children and adolescents in exceptional cases, under the care of a specialist doctor, because THC can affect brain development.

Other medicines and Bedromed drops

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This is especially important if you are taking:

- **CNS depressants** (e.g., opioids, benzodiazepines): Concomitant use with THC-containing Bedromed drops may cause additive sedation and cognitive impairment. Your doctor may need to reduce the dose of your opioid or benzodiazepine before starting Bedromed drops;
- **Anti-infective medicines** (e.g., ketoconazole, ritonavir, clarithromycin, rifampicin): These may significantly alter cannabinoid levels in your blood;
- **Anticoagulants** (e.g., warfarin): THC is a substrate of the enzyme CYP2C9, which metabolises warfarin. This may increase the risk of bleeding;
- **Anti-convulsants** (e.g., clobazam, topiramate, phenytoin): Additive central nervous system (CNS) effects or increased anti-convulsant levels may occur;
- **Antipsychotics or antidepressants** (e.g., clozapine, olanzapine, SSRIs): These may interact with cannabinoids, increasing sedation or plasma concentrations;
- **Cardiovascular medicines** (e.g., beta-blockers, antiarrhythmics, calcium channel blockers, statins): Additive cardiac effects or altered drug levels may occur.

Bedromed drops with food, drink and alcohol

Food and drink

To ensure consistent absorption and effect, always take Bedromed drops either:

- After eating, or in a fasted state (at least 2–3 hours after eating);
- Do not alternate between fed and fasted states – switching between fed and fasted states may affect how the medicine works.

Alcohol

Avoid alcohol while using Bedromed drops. Alcohol may increase THC levels in your blood, intensifying side effects such as drowsiness, dizziness, and confusion.

Pregnancy, breastfeeding and fertility

Do not use Bedromed drops if you are pregnant, planning to become pregnant, or breast feeding.

- **Pregnancy:** Bedromed drops is contraindicated during pregnancy and in people planning a pregnancy. Using cannabinoids during pregnancy may harm your baby;
- **Breast feeding:** Bedromed drops is contraindicated during breast feeding. The active ingredients can pass into breast milk and may harm your baby;
- **Fertility:** There is no information on the effects of Bedromed drops on human fertility.

Driving and operating machinery

Do not drive or operate hazardous machinery while taking Bedromed drops, (especially those containing THC), as it can slow your reaction time, make you feel dizzy, and affect your concentration.



3. How to use Bedromed drops

Always use this medicine exactly as your doctor or pharmacist has told you. Check with them if you are unsure.

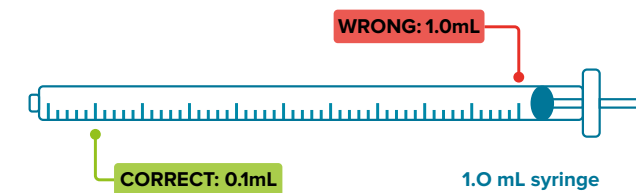
Administration instructions

Bedromed drops is for sublingual use (under your tongue):

- Shake the bottle well before each use;
- Use the syringe to place the solution under your tongue;
- Hold the liquid under your tongue for 60–90 seconds before swallowing;
- Do not drink anything for 10–15 minutes afterwards;
- Wash the syringe with clean water after each use.

Some patients - especially those who are frail, elderly, or have limited mobility - may find the syringe difficult to use. Placing the dose correctly under the tongue is important. If the dose is not placed correctly, you may receive too little or too much medicine.

Follow the instructions carefully to reduce mistakes. Take special care not to confuse **0.1 mL with 1.0 mL** - this is a ten-fold difference in dose. See the illustration below.



Dosing and titration

Always take this medicine exactly as your doctor/pharmacist has told you

Your doctor will guide you through a personalised titration schedule. General principles include:

- **Start low, go slow:** Begin with a low dose;
- **Wait before increasing:** Allow at least 60 minutes between dose increases;
- **Maximum daily dose:** Do not exceed the maximum prescribed doses per day;
- **Timing:** Take the evening dose near bedtime; the morning dose between waking and midday.

If you use more Bedromed drops than you should (overdose)

If you use more than the maximum recommended daily dose or experience concerning adverse effects, contact a doctor or emergency service immediately. Symptoms of overdose may include intense side effects (e.g., severe dizziness, confusion, hallucinations, psychosis).

If you forget to use Bedromed drops

Take the next dose as soon as you remember, unless it is almost time for your next dose. DO NOT take a double dose to make up for a missed dose.

If you stop taking Bedromed drops

Do not stop using Bedromed drops without first consulting your doctor. Your doctor may advise you to reduce your dose slowly to minimise the risk of withdrawal-like symptoms if you have been using THC-containing formulations for a prolonged period.

Return of unused medicine

If you have unused Bedromed drops (e.g., expired, discontinued, or no longer needed), return it to your pharmacist. Do not throw away any medicines via wastewater or household waste.

