

4. Possible side effects of Bedromed spray

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 formulation used (THC-only, balanced, or CBD-only).

Possible side effects by active ingredient

THC
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 (especially in predisposed individuals)
Cardiovascular effects
Arrhythmias (tachycardia or bradycardia)

CBD
Physiological effects
Sedation and drowsiness
Fatigue and lethargy
Diarrhoea
Appetite suppression and weight loss
Transient memory or attention impairment
Sleep-related effects
Insomnia
Psychological effects
Hypotension (low blood pressure), typically without arrhythmias
Cardiovascular effects
Elevated liver enzymes (transaminases) and potential liver injury at higher doses

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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.

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

Reporting of 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 spray

Storage

- Keep this medicine out of the sight and reach of children;
- Before use (unopened): Store in a refrigerator (2°C – 8°C);
- Once opened and in use: Store below 25°C;
- Store upright and keep away from heat and moisture.

Shelf life

- Unopened:** 12 months;
- Opened:** 90 days from the date of opening. After 90 days, dispose of the product responsibly. Do not use this medicine after the expiry date stated on the label.

6. Contents of the pack and other information

What Bedromed spray contains

The active ingredients are Δ^9 -tetrahydrocannabinol (THC) and/or cannabidiol (CBD). The other ingredients (excipients) are: Medium-chain triglycerides (MCT); Long-chain triglycerides (LCT); E433 - Polyoxyethylene sorbitan monooleate; E494 - Sorbitan monooleate; E202 - Potassium sorbate; E300 - Vitamin C; E307 - Vitamin E; Menthol.

What Bedromed spray looks like and contents of the pack

Bedromed spray is a sublingual spray, emulsion. It comes in a 30 mL polyethylene terephthalate (PET) container fitted with a polyethylene (PE) pump, which includes a polypropylene (PP) dip tube and a polypropylene cap. The container provides approximately 210 spray actuations (after priming).

Bedromed spray

Sublingual spray, emulsion

Patient Information

Bedromed spray

Sublingual spray, emulsion

Active ingredients

Δ^9 -tetrahydrocannabinol (THC) and/or cannabidiol (CBD)

Available fomulations

- THC 20.0 mg/mL
- THC 10.0 mg/mL + CBD 10.0 mg/mL
- CBD 20.0 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 spray is and what it is used for

What Bedromed spray contains

Bedromed spray is a sublingual spray, nanoemulsion, containing the active ingredients Δ^9 -tetrahydrocannabinol (THC) and/or cannabidiol (CBD). It is available in three formulations. Each actuation (spray) of the metered-dose pump delivers 140 microlitres (µL) of solution.

Formulation	Active Ingredients	Concentration per spray
THC only	THC 20.0 mg/mL	2.8 mg THC
Balanced	THC 10.0 mg/mL + CBD 10.0 mg/mL	1.4 mg THC + 1.4 mg CBD
CBD only	CBD 20.0 mg/mL	2.8 mg CBD

What Bedromed spray is used for

Bedromed spray 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.

Note: Formal randomised controlled trials are required to establish the safety and efficacy of Bedromed spray. Treatment must be initiated and supervised by a physician experienced in the management of the relevant patient population.



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

Do not take Bedromed spray

- If you are pregnant or are planning to become pregnant;
- If you are breastfeeding;
- If you are allergic to cannabinoids 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 spray, especially if you have:

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

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 spray may cause additive sedation and cognitive impairment. Your doctor may need to reduce the dose of your opioid or benzodiazepine before starting Bedromed spray;
- **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. If you are taking multiple other medicines (see below);
- **Cardiovascular medicines** (e.g., beta-blockers, antiarrhythmics, calcium channel blockers, statins): Additive cardiac effects or altered drug levels may occur.

Bedromed spray with food, drink and alcohol

Food and drink

To ensure consistent absorption and effect, always take Bedromed spray 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 spray. Alcohol may increase THC levels in your blood, intensifying side effects such as drowsiness, dizziness, and confusion.

Bedromed spray contains ingredients with known effect

Bedromed spray contains: E433 - polyoxyethylene sorbitan monooleate, E494 - sorbitan monooleate and methanol.



Pregnancy, breastfeeding and fertility

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

- **Pregnancy:** Bedromed spray is contraindicated during pregnancy and in people planning a pregnancy. Using cannabinoids during pregnancy may harm your baby;
- **Breast feeding:** Bedromed spray 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 spray on human fertility.

Driving and operating machinery

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

3. How to use Bedromed spray

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

Administration instructions

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

- Shake the spray container before each use;
- Direct the spray nozzle under your tongue;
- Spray the prescribed number of actuations (sprays);
- Change the application site with each administration to reduce irritation.

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 30 minutes between dose increases;
- **Maximum daily dose:** Do not exceed 15 sprays per day;
- **Timing:** Take the evening dose near bedtime; the morning dose between waking and midday.

If you use more Bedromed spray 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 spray

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 spray

Do not stop using Bedromed spray 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 spray (e.g., expired, discontinued, or no longer needed), return it to your pharmacist. Do not throw away any medicines via wastewater or household waste.

