

Cannabis-based products (part 4): Sativex®

Sativex® is the only approved cannabis-based product in New Zealand. This bulletin aims to provide information around the safety, efficacy and regulatory status of Sativex®.

What is Sativex®?

Sativex® oral mucosal spray is a pharmaceutical-grade cannabis isolate containing 2.7 mg/spray of tetrahydrocannabinol (THC) and 2.5 mg/spray of cannabidiol (CBD). It is not the same as cannabis plant, pure THC or pure CBD. Sativex® is not interchangeable with other THC / CBD combination products. See the “Cannabis-based products (part 1): an overview” bulletin for details on classification.

THC is a partial agonist of cannabinoid receptors and CBD is an antagonist of cannabinoid receptors. THC is more biologically active and therefore the effects of Sativex® appear to largely reflect the THC content.

Indications	<p><i>Refractory spasms in multiple sclerosis (MS):</i> This is an approved indication. There is moderate evidence for benefit in placebo-controlled RCTs, but the extent of benefit is very small (change of 0.11 points on the 0-4 Ashworth scale).</p> <p><i>Chronic non-cancer pain:</i> In RCTs, there was only a slight benefit over placebo with a high adverse effect rate. Studies have mainly used pure THC - there are insufficient studies using Sativex® to accurately quantify harm or benefit.</p> <p><i>Nausea:</i> There is weak evidence suggesting Sativex® is superior to placebo but no better than older antiemetics (e.g. domperidone) and with more adverse effects. It has not been compared to newer antiemetics such as ondansetron. There is more evidence for pure THC.</p>
Dosing	1 spray is 2.7 mg THC + 2.5 mg CBD. Typical starting doses are 1 or 2 sprays per day, maximum dose is 12 sprays per day. Typical maintenance doses in trials were 8 sprays per day. See datasheet and seek specialist advice.
Adverse drug effects (ADEs)	<p><i>CNS:</i> Hallucinations, euphoria (“high”), dizziness, sedation, cognitive disturbance, anxiety</p> <p><i>Gastrointestinal:</i> Nausea, vomiting, diarrhoea, increased appetite</p> <p><i>Cardiovascular:</i> Tachycardia, hypotension, platelet inhibition</p> <p><i>General:</i> Weakness, fatigue</p>
Other cautions:	<ul style="list-style-type: none"> • Associated with tolerance, withdrawal and addiction. • May impair driving and use of heavy machinery. Some industries have compulsory drug testing. • Contraindicated in pregnancy and breastfeeding. • CBD inhibits cytochrome P450 (CYP) enzymes and can interact with other medicines. • Long-term effects of THC are unknown; chronic use of the plant is associated with psychosis.
Funding	Not funded for any indication, including multiple sclerosis. Cost is approximately \$1000 / month.
Prescribing	<ul style="list-style-type: none"> • Sativex® is a class B controlled drug, and must be prescribed on a controlled drug script. • Approved for multiple sclerosis. Any prescriber can prescribe it with written approval from a neurologist. The prescription should be annotated with the indication “multiple sclerosis”. • Unapproved for all other indications. Since April 2020, ministerial and specialist approval is no longer required, however we recommend discussion with a relevant specialist as unapproved use is experimental.

Sativex® has only been trialled as an adjunct to conventional treatments and not as monotherapy. Due to the unfavourable risk / benefit profile, Sativex® is not approved for use outside of MS. Patients should be counselled that use for other indications, such as pain or nausea, is experimental.