Sativex Supply Information for Pharmacies

New Zealand Government

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What is Sativex?

Sativex is a cannabis-based product classified as a Schedule 2, Part 1 (Class B1) controlled drug product under the Misuse of Drug Act 1975. Sativex is a buccal (mouth) spray administering a metered, actuated dose containing the cannabis extracts delta-9-tetrahydrocannabinol (THC) (2.7 mg/spray) and cannabidiol (CBD) (2.5 mg/spray).

Which conditions can Sativex be prescribed for?

Sativex has consent for distribution in New Zealand as an add-on treatment for symptom improvement in patients with moderate to severe spasticity due to multiple sclerosis, who have not responded adequately to other anti-spasticity medication and who demonstrate significant improvement in spasticity related symptoms during an initial trial of therapy.

Prescribing Sativex for any other purpose is an unapproved use, and prescribing is under section 29 of the Medicines Act 1981.

Is Ministerial approval required to prescribe Sativex?

Cannabis-based products are Class B1 controlled drugs and Ministerial approval is required before these can be prescribed, supplied or administered, in accordance with regulation 22 of the Misuse of Drugs Regulations 1977.

Medical practitioners with a vocational scope of practice of Internal Medicine (specialising in neurology), registered with the Medical Council of New Zealand under the Health Practitioners Competence Assurance Act 2003, prescribing for a patient for the treatment of multiple sclerosis	• Ministerial approval to prescribe Sativex has been issued and an application is not required to be submitted for the treatment of multiple sclerosis symptoms. • The prescriber is required to state 'Multiple sclerosis' on the prescription form.
A medical practitioner registered with the Medical Council of New Zealand when acting on the written recommendation of a medical practitioner with a vocational scope of practice of Internal Medicine (specialising in neurology), for the treatment of multiple sclerosis	• Ministerial approval to prescribe Sativex has been issued and an application is not required to be submitted for the treatment of multiple sclerosis symptoms. • The name of the recommending medical practitioner with the appropriate vocational scope must be endorsed on the prescription form. • The prescriber is required to state 'Multiple sclerosis' on the prescription form.
Treatment of any other condition (unapproved use)	• Ministerial approval to prescribe is required before prescribing. Application forms can be accessed from the Ministry of Health website (www.medsafe.govt.nz/profs/riss/sativex.asp). • The approval number issued by the Ministry of Health for the specific case must be endorsed on the prescription form.

How is Sativex prescribed?

Prescriptions for Sativex must be written on a triplicate controlled drug prescription form (H572).

A prescription for Sativex, in order for it to meet legal requirements, must be:

1. A controlled drug prescription written by a neurologist and endorsed with "Multiple sclerosis",
   or;
2. A controlled drug prescription written by another medical practitioner and endorsed with "Multiple sclerosis" and the name of the recommending neurologist
   or;
3. A controlled drug prescription with a specific valid approval number relating to that prescriber and that patient.

All other legal requirements for controlled drug prescriptions also apply (as per Regulation 29 of the Misuse of Drugs Regulations 1977).

Please ensure the correct Pharmacode for Sativex is used in your pharmacy dispensing software.

Does Sativex have specific storage requirements?

Sativex needs to be stored between 2°C and 8°C (i.e. refrigerated). Regulation 28(4A) of the Misuse of Drugs Regulations 1977 exempts a pharmacy from the requirement to store Sativex in a controlled drugs safe.

Once dispensed from the pharmacy, patients should be advised to store Sativex as follows[1]:

- Do not use Sativex after the expiry date shown on the product packaging. The expiry date refers to the last day of that month.
- Store unopened Sativex upright in its carton in a refrigerator (2°C to 8°C). If it is not stored in a refrigerator it will become unstable and is unlikely to work.
- Store opened Sativex in an upright position below 25°C. Keep away from heat and direct sunlight.
- Do not use Sativex after it has been open for 42 days (10 mL).
- Unless your doctor tells you to, do not keep medicines that you no longer need.

Is Sativex funded?

Sativex is not funded by PHARMAC.

Questions

The Datasheet for Sativex is available from the Medsafe website.
https://medsafe.govt.nz/profs/Datasheet/s/sativexspray.pdf

Information on the prescribing of cannabis-based products is available on the Ministry of Health website (www.health.govt.nz/our-work/regulation-health-and-disability-system/medicines-control/prescribing-cannabis-based-products). Should you have any questions relating to the prescribing of Sativex please contact Medicines Control by email medicinescontrol@moh.govt.nz.

[1] Sativex Consumer Information Leaflet available at https://medsafe.govt.nz/consumers/cmi/s/sativex.pdf