

Sativex Supply Information for Pharmacies



New Zealand Government

31 July 2017

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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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)	<ul style="list-style-type: none">• 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).

You are required to send the red Medicines Control Copy of the triplicate controlled drug prescription form directly to the Ministry of Health to:

Medicines Control
Ministry of Health
PO Box 5013
WELLINGTON 6145

Does Sativex have specific storage requirements?

Sativex needs to be stored between 2°C and 8°C (i.e. refrigerated), but also must be stored in a controlled drugs safe by all those involved in the distribution chain (e.g. wholesalers, pharmacies). This creates a variety of logistical challenges.

The Pharmacy will need to liaise carefully with the wholesaler and patient to ensure Sativex is stored for the least time possible on their premises (within the safe) prior to collection by the patient.

Stock for future prescriptions is not be able to be purchased unless the pharmacy can store the product in a refrigerated and secured controlled drug safe at the premises.

Once dispensed from the pharmacy, patients need to store Sativex in their fridge.

Where can pharmacies order Sativex from?

From 1 August 2017, the Sponsor for Sativex in New Zealand will change to Emerge Health New Zealand Ltd.

As a result of this change, from 1 August 2017 you will be able to order Sativex stock from Healthcare Logistics via one of the following ways:

E-mail : orders@healthcarelogistics.co.nz
Fax order form to: (09) 918 5101

Any enquiries can be made by calling: (09) 969 0734

The Sativex stock will be packed carefully to maintain the cold chain as much as possible whilst in transit. The pharmacy will need to dispense the Sativex with appropriate refrigeration labelling and the patient will need to store the Sativex in their fridge once collected.

Is Sativex funded?

Sativex is not funded by PHARMAC.

Questions

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.