Sativex Supply Information for Prescribers

New Zealand Government

29 November 2016

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 an oromucosal (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. Informed consent is required from the patient for an unapproved use.

Prescribers should be aware that the clinical safety and efficacy has not been fully investigated in other medical conditions and the long-term usefulness of this medicine has not been established.

Irrespective of whether prescribing is for an approved or unapproved use, extended periods of treatment should be periodically re-evaluated to examine the long-term safety and efficacy of the medicine for the individual patient.

Are there risks of Sativex abuse and misuse?

It is unclear what proportion of patients who are chronically exposed to Sativex will develop either psychological or physical dependence. At therapeutic doses, Sativex may produce side-effects that are interpreted as a euphoria or cannabis-like "high".

As with all controlled drugs, prescribers should monitor patients who receive Sativex for signs of excessive use, abuse and misuse. Patients with a personal or family history of substance abuse (including drug or alcohol abuse) are at higher risk of addiction than other patients with chronic severe disease.

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.

What are the prescription requirements for Sativex?

Prescriptions for Sativex must be written on a triplicate controlled drug prescription form (H572). Refer to the above table for the additional endorsements required to be made on a prescription in each situation.

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.

Pharmacies will not be able to store excess Sativex, and will only be able to order stock on receipt of a valid prescription. Thus liaison between prescriber, pharmacy and patient will need to be maintained to ensure uninterrupted supply of medication. The patient will need to store Sativex in the fridge once received from the pharmacy.

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.