

Formulary Drug Listing Decisions

CANNABINOIDS (Nabilone and Sativex®)

Indications

Nabilone - management of severe nausea and vomiting associated with cancer chemotherapy

Sativex® - adjunctive treatment for symptomatic relief of spasticity in patients with multiple sclerosis (MS); adjunctive treatment for the symptomatic relief of neuropathic pain in adults with MS (conditional); adjunctive analgesic treatment in adult with advanced cancer who experience moderate to severe pain during the highest tolerated dose of strong opioid therapy for persistent background pain (conditional).

Formulary Status

The Drug Advisory Committee (DAC) recommended nabilone be listed on the cancer formulary (19WS), and Sativex® not be listed on any WSIB formularies.

The WSIB has decided to accept the DAC recommendation.

Nabilone (strengths: 0.5 mg and 1mg capsules) is listed on WSIB formulary 19WS.

Delta-9 -tetrahydrocannabinol 27 mg/ml and cannabidiol 25 mg/ml (Sativex®) buccal spray.

Overview

- Nabilone and Sativex® act on cannabinoid (CB) receptors throughout the body.
- External, independent reviews of randomized controlled studies in conditions relevant to WSIB have shown that, vs. placebo, nabilone demonstrated limited efficacy in treatment of fibromyalgia pain; improved select measures of spasticity after spinal cord injury; and produced mixed results in patients with anxiety or PTSD-related nightmares. Versus an active comparator, nabilone was somewhat efficacious for sleep disturbance in fibromyalgia (comparator amitriptyline) and offered a modest clinical effect on neuropathic pain (comparator dihydrocodeine).

- Sativex® showed superiority to placebo (but not clinical significance) in treatment of neuropathic pain and produced mixed results in combination with opioids for relief of refractory cancer pain.
- Limitations in trial design make the possible therapeutic advantages of both nabilone and Sativex® inconclusive.
- The Canadian Pain Society neuropathic pain consensus guidelines recommend cannabinoids as third-line agents in neuropathic pain and first-line agents in spinal cord injury. The recommendations were not graded according to the level of evidence and were in part based on trials in non-compensable conditions such as MS and diabetic peripheral neuropathy.
- Health Canada has issued a warning on the use of cannabinoids due to possibility of physical and psychological dependence, and potential for pharmacodynamic drug interactions with other CNS depressant drugs. Occupational hazard is also present, as cannabinoids may impair coordination and mental alertness.
- The daily cost of nabilone is slightly higher than relevant WSIB formulary alternatives, and the daily cost of Sativex® significantly higher when compared to relevant WSIB formulary alternatives. There are no pharmacoeconomic studies evaluating the cost effectiveness of nabilone or Sativex®.
- The Ontario Drug Benefit Program lists nabilone as “general benefit” under antiemetics and antinauseants. Sativex® is not listed on any provincial formularies.
- Based on the published evidence, the DAC recommended nabilone be listed on the cancer formulary (19WS) and Sativex® not be listed on any WSIB formularies.

Original date: 11 May 2009

Updated: 29 January 2013

Updated: 04 July 2016

Drug Profile

Products available in Canada:

- Nabilone (Cesamet®, various generic nabilone products)
- Delta-9 - tetrahydrocannabinol/ cannabidiol (Sativex®)