

# Information Bulletin

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## Sativex

### What is Sativex?

Sativex is the world's first prescription medicine derived from the cannabis plant. The medicine is standardized by both composition and dose and is being developed for the treatment of conditions such as spasticity in multiple sclerosis, cancer pain, and neuropathic pain of various origins

Sativex is administered as an oral spray which is absorbed by the patient's mouth. Sativex® contains active ingredients called 'cannabinoids', which are extracted from cannabis plants grown and processed under strictly controlled conditions. It is composed primarily of a 1:1 ratio of two cannabinoids-CBD (cannabidiol-a non-psychoactive cannabinoid) and THC (delta-9-tetrahydrocannabinol). The CBD:THC formulation is believed to enhance the therapeutic benefits of THC while modulating the unwanted psychotropic and other THC-related side effects, such as tachycardia. The spray delivery system keeps THC from entering the blood too rapidly and also minimizes the development of unwanted psychotropic effects.

### How does Sativex Work?

Cannabinoids react with cannabinoid receptors that occur naturally throughout our bodies, including in our brains. A receptor is a site on a brain cell where certain substances can stick or "bind" for a while. If this happens, it has an effect on the cell and the nerve impulses it produces, which causes a 'dimming down' of the symptoms of spasticity. In patients who respond to Sativex®, it is this effect which helps to improve their symptoms of spasticity and to help them cope better with their usual daily activities.

Main effects of CBD: Anti-inflammatory, anticonvulsant, antipsychotic, anti-oxidant, neuroprotective, immunomodulatory

Main effects of THC: Analgesic, anti-spasmodic, anti-tremor, anti-inflammatory, appetite stimulant, anti-emetic

### What side effects are associated with Sativex?

GW's clinical trials have generated over 1300 patient-years of safety data, and adverse events have been predictable and generally well tolerated. The most common side effects of Sativex® are dizziness, which occurs mainly in the first few weeks of treatment, and fatigue. These reactions are usually mild to moderate and improve within a few days even

if treatment is continued. These side effects are common to many other prescription medications, particularly pain medications.

### **Where is Sativex available?**

In the UK, Sativex has just been approved and launched as a prescription medicine as a treatment for spasticity due to multiple sclerosis.

In Canada, Sativex is approved under Health Canada's Notice of Compliance with Conditions (NOC/c) policy for the relief of neuropathic pain and advanced cancer pain.

In Spain, Sativex is expected to be approved shortly and launched in H2 2010. Further submissions will be made to additional European countries in H2 2010 under the mutual recognition procedure and we anticipate approvals in other European countries in H1 2011. In certain other countries, Sativex® is available on prescription on a named patient basis. In total, Sativex has been exported to 28 countries either for named patient prescription use or for clinical trials purposes.

In the US, Sativex® is an investigational drug being developed as an adjunctive (additive) analgesic treatment for patients with advanced cancer whose persistent pain has not been adequately relieved by optimized treatment with strong opioids. The FDA has not approved Sativex® and the product is not available in the United States other than for use in FDA approved clinical trials.

Sativex is not currently available in Ireland. Under the Misuse of Drugs Act 1977 the product can not be prescribed in Ireland as the drug derives from the cannabis plant.

### **What has the Research Shown?**

In March 2009 GW Pharmaceuticals announced results of two clinical trials involving Sativex and its effect on spasticity in people with MS. A phase III study involved 573 people with MS who were affected by spasticity and had not responded to existing therapies. Participants in the study were given Sativex for four weeks. Those who responded to the treatment (241 of the original 573 people) continued to be given either Sativex or a placebo (dummy treatment), for a further 12 weeks. Throughout the trial, participants were not allowed to exceed a fixed dose of the medication.

- 74% of people who continued treatment with Sativex achieved an improvement of greater than 30% in their spasticity score compared with 51% of people who were given the placebo treatment
- There were also significant reductions in spasms and sleep disturbances and an improvement in the overall impression of change in the study participants.

Another small study involved 36 people with MS who had been taking Sativex for an average of three and a half years. The participants either continued treatment with Sativex, or were given a placebo treatment for four weeks. At the end of the study, people on the placebo treatment and their carers reported worsening spasticity compared with people taking Sativex. Although the results have been reported as statistically significant, GW Pharmaceuticals did not indicate by how much spasticity was reduced in people taking Sativex. One of the primary aims of this study was to assess withdrawal symptoms as a result of terminating long-term use of Sativex. Results from this trial have indicated very few withdrawal symptoms as a result of terminating Sativex even after several years use.

## **What does MS Ireland think of the use of cannabis and Sativex?**

MS Ireland does not condone any illegal activity. However, anecdotal evidence suggests that some people with MS are breaking the law to obtain cannabis in an effort to alleviate their symptoms. MS Ireland believes that ordinary, up-standing members of society should not be forced into this situation and Sativex, a safe and thoroughly tested product, should be made available to those with MS who need it.

MS Ireland wrote to Minister Harney in July 2010, asking her to review the legislation and make Sativex available in Ireland. While we received a call asking to take part in a review panel, nothing has happened since. MS Ireland has written to Minister O'Reilly now asking for the panel to be convened as soon as possible. Check on our website for updates as they become available.

### **Sources:**

This information has been taken from <http://www.gwpharm.com> and [www.mssociety.org.uk](http://www.mssociety.org.uk)

### **Disclaimer:**

MS Ireland provides information to the MS Community on an array of topics associated with MS. This information is for reference purposes only and medical advice should always be sought before any treatment or intervention is tried.