

# July 2022 Newsletter



## Sativex – The Road to FDA Approval

The Food and Drug Administration (FDA) has approved many treatments for MS to help modify the disease course, treat relapses and manage symptoms, but none are completely effective. Many people living with the disease continue to experience flares, disease progression, and ongoing symptoms. Some turn to [alternative medicine](#) to manage their symptoms and increase their quality of life, most often in combination with their prescribed MS treatments. One such treatment is [cannabis](#), or marijuana.



There are many types of chemical compounds in cannabis. [Flavonoids](#) are a large family of compounds found in most fruits and vegetables, in large part responsible for their vivid colors. They are important because they have been shown to have beneficial anti-inflammatory and antioxidant effects. [Terpenoids](#) (or terpenes) are aromatic chemicals responsible for marijuana's unique smell. [Cannabinoids](#) are the chemical compounds that, when consumed, bind to cannabinoid receptors in the human body and alter nerve transmission in the brain (resulting in marijuana's psychological effects). The two major cannabinoids in cannabis that have been studied are [tetrahydrocannabinol](#) (THC) and [cannabidiol](#) (CBD). THC is thought to cause most of the psychological effects of cannabis.

CBD has significant medical benefits, but does not make people feel “stoned” and can actually counteract the psychological effects of THC.



[Sativex](#) (Nabiximols) is a cannabis extract mouth spray that contains equal quantities of THC and CBD. It is used outside the United States for the treatment of MS-related spasticity when a person has shown inadequate response to other treatments or found their side effects intolerable. Sativex can be used in addition to a person's current anti-spasticity medication. It is administered on the inside of the cheek or under the tongue. The optimum dose varies from person to person, so a titration period is needed when beginning treatment. During this phase, the number of sprays is increased each day until the most effective dose is achieved. This can take a few days or up to two weeks. The most commonly reported side effects are dizziness, drowsiness, diarrhea or constipation, fatigue, memory or concentration problems, and a dry mouth or changed sense of taste. These reactions are usually mild to moderate and resolve after the initial titration period. Sativex is not recommended for pregnant women and people under 18 years old, or those with a history of [psychotic conditions](#).

Sativex is approved for treatment of MS-related spasticity in Canada, New Zealand, and several European countries. The therapy’s approval abroad was supported by data from three Phase 3 clinical trials.

### Research supporting Sativex’s approval in Europe:

		
<b>2007</b> Investigators concluded that cannabis-based medicine may represent a useful new agent for the treatment of MS spasticity.	<b>2011</b> Researchers demonstrated the efficacy and safety of Sativex for treating MS spasticity.	<b>2018</b> Results showed add-on Sativex provided better relief of resistant MS spasticity compared to antispasticity medication alone.

Recent research in Europe has revealed more about Sativex’s effectiveness and side effect profile post-approval. [Investigators](#) in Italy looked at 1,597 people with MS who had started treatment with Sativex for spasticity. They found that 23% of participants stopped treatment because it wasn’t effective and 16% because of side effects. The most common side effects were cognitive and psychiatric effects, fatigue and drowsiness. The researchers concluded that the first six weeks of treatment are useful in identifying those individuals in which Sativex could be effective. Another [study](#) analyzed data from 941 people with MS who were prescribed Sativex in the UK, Germany and Switzerland. Results show approximately 80% of participants benefitted from treatment and 30% stopped treatment because of lack of effectiveness or side effects. The most common side effects were dizziness and fatigue, and people were more likely to experience these during the first month of treatment.



Scientists have also looked at using Sativex to treat other MS symptoms. For example:

	
<p><b>2010</b></p> <p>Although their findings were not statistically significant, investigators in the UK and Belgium concluded that Sativex treatment improved bladder dysfunction.</p>	<p><b>2018</b></p> <p>Italian researchers found Sativex treatment significantly reduced pain and abnormal cold perception in people with MS.</p>

A [Phase 3 clinical trial](#) is underway in the United States to demonstrate the effectiveness of Sativex, compared with placebo, in the treatment of muscle spasms associated with MS. The estimated completion date for this study is February 2023. Investigators expect to

enroll about 446 adults with MS and spasticity at 28 study locations across the United States, the Czech Republic, Poland and the United Kingdom.

Participants will be randomly assigned to either Sativex treatment or a placebo, both self-administered twice daily as an oral spray in addition to standard of care. Participants will record their



daily number of muscle spasms in an electronic diary. The study will have three phases: a 4-week “baseline” period to establish a reference point, a 12-week treatment period (a 2-week titration phase and 10 weeks at the optimum dose), followed by a 2 weeks of follow-up evaluations, for a total of 18 weeks. Investigators will evaluate changes from baseline in participants’ average daily spasm count and [Multiple Sclerosis Spasticity Score](#) (MSSS-88), among other parameters. [Future clinical trials](#) are planned to further assess the drug’s effectiveness at reducing muscle spasm frequency and treating increased muscle tone. Researchers are hopeful that these trials will pave the way for FDA approval of Sativex for the treatment of MS spasticity in the United States.

Researchers are working to better understand the benefits and potential risks of cannabis as a treatment for MS and its symptoms. iConquerMS was developed to engage people with MS to drive and shape research on topics like this that are of great interest to the MS community. The data provided by network members are a valuable resource, giving investigators insight into the effectiveness of MS treatments, both from the clinical and personal perspectives. If you haven’t already done so, please consider [joining](#). With your participation and support, we can add to the pool of [real-world data](#) that researchers have to draw from for these important studies and help improve quality of life for everyone living with the disease.

**You know your MS better than anyone**

Take surveys about your daily experiences and symptoms to help create a large pool of data for multiple sclerosis researchers.

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