

<p style="text-align: center;">APPROVAL OF SATIVEX[®] WITH CONDITIONS FACT SHEET</p>
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What is SATIVEX[®]?

SATIVEX[®] is a cannabis based medicine containing Tetranabinex[®] and Nabidiolex[®] extracts of chemically and genetically characterised *Cannabis sativa* L. plants. The principal active components are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD).

Health Canada has approved SATIVEX[®] with conditions, under the Notice of Compliance with Conditions (NOC/c) policy. This authorisation reflects the promising nature of the clinical evidence which must be confirmed with further studies. Products approved under Health Canada's NOC/c policy, have demonstrated promising benefit, are of high quality and possess an acceptable safety profile based on a benefit/risk assessment for the approved use.

What is SATIVEX[®] used for?

SATIVEX[®] is used for the adjunctive treatment for the symptomatic relief of neuropathic pain in multiple sclerosis in adults.

What is multiple sclerosis?

Multiple sclerosis (MS) is a degenerative neurological condition, which is associated with a wide range of distressing and disabling signs and symptoms. One of the distressing symptoms is neuropathic pain.

How does SATIVEX[®] work?

Sativex is thought to act via cannabinoid receptors that are distributed throughout the central nervous system and in immune cells. SATIVEX[®] contains Tetranabinex[®] and Nabidiolex[®], extracts of chemically and genetically characterised *Cannabis sativa* L. plants (hemp plants). The exact mechanism of action in relieving neuropathic pain is not known.

What other treatments have been used to treat neuropathic pain in multiple sclerosis?

SATIVEX[®] is the only drug approved in Canada for adjunctive use in this condition.

What do patients need to know about using SATIVEX[®]?

SATIVEX[®] causes irritations in the mouth in 20 – 25% patients in clinical trials. Patients may also experience symptoms of cannabinoid intoxication, including dizziness when they first take SATIVEX[®]. Fainting episodes have been reported as well as feeling

drunk, disturbance in attention, dizziness, somnolence, disorientation, dissociation and euphoric mood. THC can cause symptoms such as changes of mood, decrease in cognitive performances and memory, decrease in ability to control drives and impulses, and alteration of the perception of reality, particularly altered time sense. Patients should start from low doses and adjust their doses gradually to get the optimal balance of a good control on their neuropathic pain and minimal intoxication.

SATIVEX[®] may impair ability to carry out complicated tasks. Patients should not drive or engage in activities requiring unimpaired judgment and coordination.

Some drugs are broken down in the liver by the same route as SATIVEX[®], so patients must inform their physician if they are taking other drugs.

What are the side effects and how serious are they?

Side effects are mild to moderate and mainly consist of either application site reactions in the mouth (such as dry mouth, stinging) or intoxication (such as dizziness, disorientation or impaired memory). There may be sickness or diarrhoea.

Patients should report all new symptoms after beginning using SATIVEX[®] to their doctor. Not all new symptoms are caused by SATIVEX[®], but SATIVEX[®] may be responsible for some new symptoms.

Who can be treated with SATIVEX[®]?

Patients over 18 years old with multiple sclerosis can be treated with SATIVEX[®]. If used for treating the elderly, there are no special precautions; however, frequent review by the clinician is recommended.

Who should not take SATIVEX[®]?

- patients with known or suspected allergy to cannabinoids, propylene glycol, ethanol or peppermint oil
- patients with significant hepatic or renal impairment
- patients with serious cardiovascular disease, such as ischaemic heart disease, arrhythmias, poorly controlled hypertension or severe heart failure
- patients with a history of schizophrenia or any other psychotic disorder
- children under 18 years of age.
- women of child-bearing potential not on a reliable contraceptive or men intending to start a family .
- pregnant or nursing women.

How is SATIVEX[®] taken?

SATIVEX[®] is a solution supplied in small vials as a buccal spray. The patient takes the spray, directed under the tongue or inside of the cheeks, cautiously establishing the best dose for reducing their pain through titration up to a tolerated dose.

What else should patients know about taking SATIVEX[®]?

Patients should be aware that alcohol is not recommended during SATIVEX[®] therapy. SATIVEX[®] contains alcohol. The central effects of SATIVEX[®] and alcohol in drinks may make the patient more impaired.

The patient and their partner must ensure reliable contraceptive precautions are taken during treatment with SATIVEX[®] and for at least three months after they stop taking SATIVEX[®].

Where can I learn more about SATIVEX[®]?

For medical enquiries, contact Bayer Inc. at 1-800-265-7382.
Or visit Bayer's website at: www.bayerhealth.ca

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