

AUTHORIZATION WITH CONDITIONS OF ^NSATIVEX[®] (Tetranabinex[®] and Nabidiolex[®])

SATIVEX[®] MAY BE USEFUL AS ADJUNCTIVE ANALGESIC TREATMENT IN ADULT PATIENTS WITH ADVANCED CANCER WHO EXPERIENCE MODERATE TO SEVERE PAIN DURING THE HIGHEST TOLERATED DOSE OF STRONG OPIOID THERAPY FOR PERSISTENT BACKGROUND PAIN

FACT SHEET

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. SATIVEX[®] is indicated as adjunctive analgesic treatment in adult patients with advanced cancer who experience moderate to severe pain during the highest tolerated dose of strong opioid therapy for persistent background pain. This authorization reflects the promising nature of the clinical evidence of efficacy and safety which must be verified 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?

This current conditional approval for SATIVEX[®] is for adjunctive analgesic treatment in adult patients with advanced cancer who experience moderate to severe pain during the highest tolerated dose of strong opioid therapy for persistent background pain.

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

What is advanced cancer?

Advanced cancer is a cancer that may have spread to other places in the body than its origin and usually cannot be cured or controlled with treatment.

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 or cancer pain is not known.

What other treatments have been used as adjunctive analgesic treatment in adult patients with advanced cancer who experience moderate to severe pain during the highest tolerated dose of strong opioid therapy for persistent background pain?

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

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

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

While taking SATIVEX[®] you should not drink alcohol or take other drugs which may have an effect on the central nervous system such as sedatives or hypnotics, without consulting your doctor, as these products have a further additive effect on some of the symptoms listed above.

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 or central nervous system effects. They may include dry or sore mouth, feeling or being sick, discomfort and stinging in the mouth or mouth ulcers, tiredness, drowsiness, confusion, dizziness or faintness, disorientation, poor concentration and/or impaired memory, hallucinations or strange ideas, a feeling of unreality, feeling abnormal or drunk, poor balance, slurred speech, depressed mood, depression, feeling people are against you and a feeling of general happiness or a “high” (easy laughing, heightened awareness).

Other side effects may include rapid heart beat, vertigo, blurred vision, abdominal pain, feeling ill, constipation, diarrhoea, indigestion, falls, weakness, thirst, tooth discolouration, throat infection, flu, upset stomach, increase or decrease in appetite, headache, muscle spasticity, flushing, a sensation of heaviness, abnormal taste, cough, throat irritation or high or low blood pressure. There may also be side effects of stomach pain, disturbance in attention, panic attacks or urinary retention.

Stinging or discomfort in the mouth may be experienced if SATIVEX[®] is sprayed in the same place in the mouth on repeated occasions. This is usually overcome by varying the area in the mouth where SATIVEX[®] is sprayed.

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 advanced cancer who experience moderate to severe pain during the highest tolerated dose of strong opioid therapy for persistent background pain can be treated with SATIVEX[®]. If used for treating the elderly, there are no specific 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 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. 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