ASKATCHEWAN DRUG INFORMATION SERVICE
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SATIVEX® Fact Sheet

What is Sativex®?
Sativex® is a new buccal spray containing delta-9-tetrahydrocannabinol (THC) (27 mg/mL) and cannabidiol (CBD) (25mg/mL).[1] The drug was developed by GW Pharmaceuticals in the UK and Bayer has received exclusive marketing rights in Canada.[2] Canada is the first country to approve Sativex®[2.] The Health Protection Branch has granted the drug a Notice of Compliance with conditions (NOCc).[3] NOCc's are granted for drugs with promising benefit and acceptable safety profiles. Because of the conditions, Bayer must submit further data from clinical trials to Health Canada before the conditions will be removed. [3]

How does it work?
While the exact mechanism of action is unknown, Sativex® most likely acts on the cannabinoid receptors.[1] In animals, CBD reduced unwanted side effects associated with THC while adding to the analgesic activity.[3]

What is its indication?
Sativex® is indicated as an adjuvant treatment of the symptoms of neuropathic pain ONLY for patients with Multiple Sclerosis.[1] The drug, in varying ratios of THC:CBD, is being investigated in other patient populations such as: those with neuropathic pain from cancer and spinal cord injuries; inflammatory bowel disorders; schizophrenia; various CNS disorders such as epilepsy; relief of pain and inflammation in rheumatoid arthritis; and others.[4] At this time Sativex® has not been approved for use in these patients.

What have the clinical trials shown?
Only one Phase III clinical study involving 66 participants has been carried out looking at THC/CBD in patients with neuropathic pain from MS. [4] This was a double-blind, randomized, placebo-controlled study in which Sativex® showed a statistically significant reduction in pain and sleep disturbances.[1] Over 424 patients have been enrolled in trials for various neurological conditions.[2] Of these, 110 patients have received THC/CBD for more than a year.[2] The Medicines and Healthcare Products Regulatory Authority (MHRA) in the UK has not approved Sativex® citing concerns of results not being clinically relevant.[5]

Place in Therapy
To date, there have been no head-to-head trials with Sativex® and other agents used for neuropathic pain (such as TCA's, anticonvulsants, analgesics or topical antineuralgics). Therefore, it is difficult to ascertain the efficacy of Sativex® compared to these alternative agents. However, Sativex® does offer flexible dosing of THC without the contaminants of smoked marijuana.

What is the dosing of Sativex®?[1]
The spray is to be directed under the tongue or toward the cheeks. The spray should be administered to different areas of the mouth to prevent mucosal irritation. The initial dose is one spray every four hours as needed to a maximum of four sprays on the first day. Subsequently, the patient should titrate to the dose required for pain relief. The median

dose in trials was five sprays daily. As with other narcotic drugs, patients may require and tolerate higher doses.

Procurement and Dispensing Issues
Sativex® is available in vials of 5.5mL each containing 51 metered doses.[1] The drug is only available by direct order through Bayer (1 800 268-1432) and comes in cartons of four vials.[6] The acquisition cost is $125 per vial.[6] THC and CBD are both listed on the schedule to the Narcotic Control Regulations.[7] As such, Sativex® is subject to regulations pertaining to the Act.

Further Information
The product monograph for Sativex® is available on Bayer's website at www.bayerhealth.ca

Correction: to SDIS Drug News (Vol 22, No 2, June 2005 Insulin Glargine). Lantus® is not available in the 3ml pen cartridge. Currently, Aventis only markets the 10ml vial of Insulin Glargine® in Canada. We apologize for any inconvenience this may have caused.

Prepared by Carmen Bell, Drug Information Consultant

References

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