

SPRAY III Clinical Research Study Patient Fact Sheet

WHAT IS THE SPRAY III STUDY?

The SPRAY III study is a Phase 3 clinical study for patients whose chronic cancer pain is not totally relieved by their current pain medication. The SPRAY III study will determine whether Sativex® (nabiximols) is effective in helping manage chronic cancer pain in addition to opiate pain medication.

WHAT TREATMENT WOULD I RECEIVE IN THE SPRAY III STUDY?

- Study participants are randomly assigned to receive either Sativex® or placebo (a mouth spray that does not contain any active medication).
- Study participants have a 50 percent chance of receiving treatment with Sativex® as opposed to treatment with placebo.
- People who qualify for the study will receive study-related medical evaluations, tests and the investigational medication or placebo.

WHAT SHOULD I KNOW ABOUT THE SPRAY III STUDY MEDICATION?

- Sativex® is considered an investigational medication because it has not been approved by all the necessary regulatory agencies where this study is taking place. Sativex® has already been approved in Canada as an adjunctive treatment for chronic cancer pain for patients already on opiate medication.
- In this study, Sativex® comes in the form of a mouth spray taken by spraying it in your mouth on the inside of your cheeks.

HOW LONG IS THE SPRAY III STUDY?

- The study will last approximately 9 weeks and include four visits to the study clinic and one follow-up phone call.
- Each clinic visit will last about 2 hours, at which time you will undergo a series of medical tests and evaluations to monitor your safety and progress.
- You will also need to call an automated telephone number on a daily basis to record your level of pain, your sleep disruption (if any) and your study medication usage.

After completion of the 9-week study, you may have the option to enter an extension study which provides continued availability of Sativex®.

AM I ELIGIBLE TO PARTICIPATE IN THE SPRAY III STUDY?

To be eligible for the SPRAY III study, you must:

- Be 18 years of age or older
- Have cancer
- Have a clinical diagnosis of chronic cancer pain
- Be currently taking opiate treatments, such as morphine or oxycodone, but still having trouble managing your pain

Additional requirements for study eligibility will be assessed by the study doctor.

PLEASE NOTE THAT AT ALL TIMES DURING THE SPRAY III STUDY, PARTICIPANTS WILL CONTINUE TAKING THEIR OPIATE PAIN MEDICATIONS.

