

## Points to Consider:

- You may not receive any health benefit or improvement in your condition by participating in any research studies.
- Others may benefit in the future from the information gathered from research studies.
- Taking part in research is entirely voluntary. You may change your mind and end your participation at any time and for any reason.

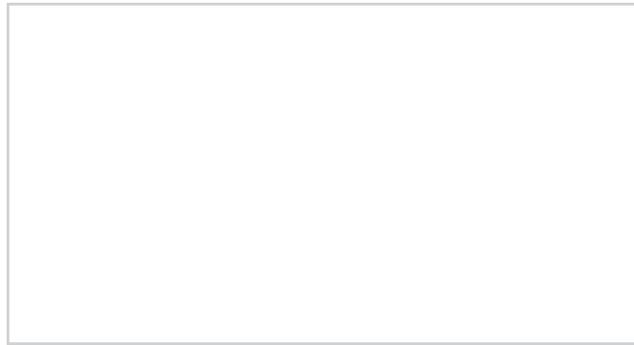
## Questions to Ask your Study Doctor:

- What will be expected from me if I participate in this research study?
- What are the possible side effects of the study medication or study procedures?
- What other treatment options are available to me?
- If I participate in the study, will I be restricted from any activities or medical treatments?
- Are the costs for study-related procedures, medications and laboratory tests covered as part of my participation?

## Are there risks of joining a clinical trial?

The study drug is not currently approved. All medications have side effects. The study doctor will explain the side effects of the study drug to you.

If you or a loved one would like to receive more information about this study, please contact the study site below:



In treating Parkinson's Disease, tomorrow's breakthroughs begin with today's research

B7601003: An investigational study for the treatment of Parkinson's Disease

**If you or a loved one currently experience motor fluctuations due to Parkinson's disease you may want to talk to your doctor about a clinical study of an investigational medication for the treatment of Parkinson's disease.**

## **You might think there isn't anything you can do about Parkinson's. BUT THERE IS.**

Parkinson's disease affects millions of people worldwide and there is currently no cure. While Parkinson's disease itself is not fatal, the complications that arise from it can be. As it continues to progress over time, the symptoms associated with Parkinson's greatly affect quality of life, making it difficult to do everyday tasks like walking, talking, or swallowing. Researchers continue to look for treatments and a possible cure for this disease. If you have been diagnosed with Parkinson's disease, you might be eligible to participate in our clinical research study.

## **About This Study**

This research study is being conducted at approximately 60 different research sites in about 5 countries. The purpose of this research study is to evaluate the safety and the effects of different doses of the investigational medication or placebo taken with Levodopa (L-Dopa) as a treatment for Parkinson's disease.

Participants in the study may receive either the investigational drug or a placebo to take along with L-Dopa. A placebo looks like the investigational drug but does not contain any drug. Researchers use a placebo to see if the study drug works better or is safer than not taking anything. Neither you nor the study medical staff will know if you receive the investigational drug or the placebo. This is done to make sure the results of the study cannot be unfairly influenced by anyone. In case of urgent need, the study team can learn quickly if you are receiving the investigational drug or placebo.

## **Participant Eligibility**

**To be eligible to participate in this study you must meet several criteria including the following:**

- You are a male or female between the ages of 45 to 85 with Parkinson's disease
- You are on a daily dose of at least 400mg of L-Dopa
- You experience motor fluctuations
- You are able to recognize "wearing off" symptoms
- You are willing to take the study drug as directed and participate in study tests and procedures
- You are willing to attend 13 clinic and 4 phone visits over the duration of the study—up to 23 weeks.

## **About the Investigational Drug**

The investigational medication is not approved by the U.S. Food and Drug Administration (FDA) or by any other responsible regulatory agencies around the world. Regulatory agencies, including the FDA, require that before an investigational drug can be made available to the public, it must undergo a series of clinical research studies in a population of subjects large enough to evaluate safety, tolerability and effectiveness. The processes and procedures to be followed in this study have been reviewed by the U.S. FDA and Institutional Review Boards and/or Ethics Committees. An Institutional Review Board (IRB), sometimes referred to as an Institutional Review Committee or Ethics Committee, is a group of assigned individuals from different backgrounds and professions who are formally designated to review, approve and periodically assess the suitability of the clinical trial, including the information subjects and their families are given about the procedures, possible benefits and risks of a subject's participation in the trial. The primary purpose of the IRB's activities is to ensure the protection of the rights and welfare of the volunteers.

## **Participating in a Clinical Trials**

A clinical trial is a study conducted under controlled and monitored conditions. An investigational drug is a drug that is still being tested for use in humans and is not approved for sale. Before a study drug can be made available, clinical trials have to be carried out to see if the study drug is safe and effective.

Participating in a clinical trial is totally voluntary and no one can make you join. Volunteers participate in clinical studies for different reasons. The reasons to participate may include: a desire to help others with the same disease or condition in the future, the ability to receive an investigational drug not yet available, and the opportunity to be part of the advancement of medical research.

## **Your Rights as a Participant**

It is up to you to decide if you wish to participate in this study. It is not possible to know whether the study drug will have a beneficial effect—that is the purpose of the study. You are encouraged to discuss your possible participation in the study with your physician and with your family or caregiver. If you qualify, and choose to participate, your participation is always voluntary. You may withdraw from the study at any time and for any reason. This will not affect your care in the future or affect any benefit to which you are otherwise entitled.

Before participating in the study, you must provide your consent to participate. As part of this process, you will be asked to review and sign an "informed consent" document. The document provides all of the details, procedures and known risks associated with the study. You should expect the research site to fully explain and discuss the contents of the document with you. Signing the consent document means that you understand the study and its requirements, potential benefits and known risks, and that you agree to participate in the study. Protecting your privacy is important to the site staff and the sponsor of the study. Measures are in place to protect your private information.