



ARTISTS 2 Research Study  
for Children and Adolescents with

# Tourette Syndrome

Patient Welcome Guide

**THANK YOU** for being a part of this research study. With your help, doctors and researchers hope to learn more about the investigational drug and its effects on Tourette syndrome.

This welcome guide has information that will help you during the study. You can learn more details about the investigational drug (TEV-50717) and placebo, your responsibilities, and what will happen at your study clinic visits.

You will be in this study for about 5½ months. You will come to the study clinic up to 6 times so that doctors and the study staff can check your health. You will also receive up to 5 phone calls from the study staff during the study.

If you can't come to a scheduled study clinic visit, please let us know. Or have your parents/guardians call us so that we can reschedule your clinic visit.

If your personal contact information (or your parents/guardians' information) changes, please let us know as soon as possible. This will help us keep in touch with you and help you in the study.

If you have questions during the study, please ask the study doctor or study staff. We are always happy to help you.

Thanks again.

Your **ARTISTS 2** Study Staff

## About the Investigational Drug

The investigational drug is a new formula of a prescribed medication that is used to treat Tourette syndrome. It is being studied as a possible treatment option for tics associated with the disorder.

When compared to the prescribed medication, the investigational drug has similar effects on tics. However, it may produce fewer side effects, which might make it easier to take.

The investigational drug is not approved to treat Tourette syndrome. You can only get the investigational drug in this study.

You have a 2 in 3 chance (66.7%) of getting the investigational drug in this study. If you do not get the investigational drug, you will get placebo.

You have a 1 in 3 chance (33.3%) of getting placebo. Placebo looks like the investigational drug, but has no active medicine in it.

It is possible your study drug (investigational or placebo) could make you feel bad. If you start to feel bad, please tell the study doctor, the study staff, or your parents/guardians right away.

## Study Drug Use Reminders

- Take your study drug twice a day
- You should swallow your study drug tablet whole
- Take your study drug with food (a meal or snack)
- Do not take your study drug on an empty stomach
- The study staff will give you and your parents/guardians instructions on how to take your study drug at home
- You and your parents/guardians will be given a study diary
- You should write down when you take your study drug in this diary
- Remember to bring your unused study drug and blister packs every time you come to a study clinic visit

## Study Responsibilities

- You do not have to be in this study if you don't want to
- You are free to leave this study at any time
- If you leave the study, it won't affect your medical care
- Please follow all instructions from the study doctor and study staff
- You should come to all scheduled study clinic visits
- Honestly answer any questions the study doctor or study staff asks
- Tell someone if you start to feel bad
- Ask questions about anything you don't understand

# Study Center Visit Tests

This section will help you know more about your study clinic visits.

## Prescreening

*It is possible you will be asked to go through a Prescreening period in which you will stop taking certain medications. The Prescreening period could last up to 3 months prior to Day 1.*

- Read and sign the informed consent form (ICF)

## Screening Visit (Visit 1)

This visit will help the study doctor and study staff decide if you can be in the study.

At this visit, the study doctor and/or study staff will:

- Ask you and your parents/guardians to read and sign the informed consent form (ICF)
- Decide if you can be in the study
- Look at your medical history
- Take your blood pressure, pulse, breathing rate, and body temperature
- Measure your height and weight
- Give you a physical exam
- Test your reflexes
- Perform an electrocardiogram (tells the doctor about the condition of your heart)
- Take some blood to do some tests
- Ask for a urine sample
- Ask you to answer questions about your Tourette syndrome
- Ask how you are feeling
- Ask about medications you are taking

## Day 1 Visit

*You will be given a blister pack of your study drug to take at home on days when you do not visit the study clinic.*

At this visit, the study doctor and/or study staff will:

- Decide if you can still be in the study
- Take your blood pressure, pulse, breathing rate, and body temperature
- Measure your weight
- Perform an electrocardiogram (tells the doctor about the condition of your heart)
- Ask for a urine sample (females only)
- Ask you to answer questions about your Tourette syndrome
- Give you and your parents/guardians a supply of your study drug to take home
- Give you and your parents/guardians a study diary to take home and complete when you take your study drug
- Ask how you are feeling
- Ask about medications you are taking

At Week 1, the study staff will call you and your parents/guardians. They will ask you about how you are feeling, your study drug dose, and what medications you are taking.

## Week 2 Visit

*Please remember to bring any unused study drug and your study diary to this visit.*

At this visit, the study doctor and/or study staff will:

- Ask about your study drug dose
- Take your blood pressure, pulse, breathing rate, and body temperature
- Measure your weight
- Ask you to answer questions about your Tourette syndrome
- Ask you to return your unused study drug
- Ask you to return your study diary
- Ask questions about taking your study drug
- Ask you how you are feeling
- Ask you about medications you are taking
- Give you and your parents/guardians a supply of your study drug to take home
- Give you and your parents/guardians a study diary to take home for completion

At Week 3, the study staff will call you and your parents/guardians. They will ask you about how you are feeling, your study drug dose, and what medications you are taking.

## Week 4 (Visit 4)

*Please remember to bring any unused study drug and your study diary to this visit.*

At this visit, the study doctor and/or study staff will:

- Take your blood pressure, pulse, breathing rate, and body temperature
- Measure your weight
- Perform an electrocardiogram (tells the doctor about the condition of your heart)
- Ask you to answer questions about your Tourette syndrome
- Ask you to return your unused study drug
- Ask you to return your study diary
- Ask questions about taking your study drug
- Ask you how you are feeling
- Ask you about medications you are taking
- Give you and your parents/guardians a supply of your study drug to take home
- Give you and your parents/guardians a study diary to take home for completion

At Weeks 6 and 7, the study staff will call you and your parents/guardians. They will ask you about how you are feeling, your study drug dose, and what medications you are taking. There are no tests and assessments at Week 5, and you will not receive a phone call from the study staff.

## Week 8 Visit

*Please remember to bring any unused study drug and study diary to this visit. You will not receive any more of your study drug.*

At this visit, the study doctor and/or study staff will:

- Take your blood pressure, pulse, breathing rate, and body temperature
- Measure your height and weight
- Give you a physical exam
- Test your reflexes
- Perform an electrocardiogram (tells the doctor about the condition of your heart)
- Take some blood to do some tests
- Ask you to answer questions about your Tourette syndrome
- Ask you to return your unused study drug
- Ask you to return your study diary
- Ask questions about taking your study drug
- Ask you how you are feeling
- Ask you about medications you are taking

## Week 9 Visit (Follow-Up)

*This is your last study clinic visit.*

At this visit, the study doctor and/or study staff will:

- Take your blood pressure, pulse, breathing rate, and body temperature
- Measure your weight
- Ask you to answer questions about your Tourette syndrome
- Ask you how you are feeling
- Ask you about medications you are taking

At Week 10, the study staff will call you and your parents/guardians. They will ask you about how you are feeling and what medications you are taking.

For questions about any of the tests in this study, please ask the study doctor or the study staff.



## ARTISTS 2 Research Study Contact Information

Study Doctor's Name: Dr. Gianni Faedda, MD

Study Doctor's Telephone Number: 646 - 838 - 5111

Study Coordinator's Name: Moodcenter \_ NYC

Study Coordinator's Telephone Number: 646 - 838 - 5111

In the event of a medical emergency, please seek immediate medical attention. Be sure to have your parents/guardians call the study doctor as soon as possible.

