YOUR FIRST DAY ON GILENYA
A handy guide to getting started

If you and your health care professional decide to move forward with treatment, you’ll take a few up-front tests to make sure that GILENYA® is a good fit. These include a blood test, an eye exam, and an electrocardiogram (ECG). Children 10 years and older should complete their vaccination schedule before starting GILENYA.

When it comes to starting GILENYA, your health care professional will choose where you will have your first dose:
• A doctor’s office
• The GILENYA Assessment Network (GAN), which allows for you to take these tests and the first dose at one of our GILENYA@Medical Facility sites (a local medical office or facility), or in the comfort of your own home through GILENYA@Home

Please see Important Safety Information on pages 3-6.
Please see Important Product Information, including Medication Guide, on gilenya.com.
YOUR FIRST DAY ON GILENYA (CONT.)

Take 6 (hours, that is)

After you take your first dose, your health care team will check your pulse and blood pressure each hour for at least 6 hours while you relax.

Why Your Heart Activity Is Monitored

When you take your first dose of GILENYA®, it’s expected that your heart rate will slow down temporarily. In clinical studies, less than 1% of adults experienced symptoms due to slow heart rate. For most people, slow heart rate begins to return to normal after 6 hours and usually fully returns to normal within 1 month.

When these symptoms did occur, it was usually during the first 6 hours after the first dose of GILENYA (although they can occur up to 24 hours after). Most people don’t need treatment for a slow heart rate, but some do. Symptoms of slow heart rate include dizziness, tiredness, chest pain, and feeling like the heart is beating slowly or skipping beats.

Remember, symptoms of slow heart rate typically happen when you start on GILENYA. If these symptoms occur after you’ve taken your first dose, you should call your health care professional or go to the nearest emergency room right away if you feel any of the symptoms of slow heart rate listed above.

If you have any serious side effects after your first dose, especially those that require treatment with other medicines, you will be watched overnight, and for at least 6 hours following your second dose. If you have certain heart problems, or are on certain medicines that can affect your heart, you will be watched overnight after you take your first dose of GILENYA.

Things to do during your 6 hours

- Read a book or magazine
- Watch a movie
- Speak out with the GILENYA community on Facebook facebook.com/GilenyaGO
- Tweet @GILENYAUSOnly using #GILENYA
- If you’re starting with GILENYA@Home, you can work from home, cook, or do light household tasks (as long as you stay inside your house)

Get a second ECG

At the end of your 6 hours, you’ll have another ECG. If all looks good, you can make GILENYA part of your daily routine. If after 6 hours your ECG shows any heart problems, you will need additional observation. If you are doing GILENYA@Home, you will need to be moved to a medical facility for continued observation.

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YOUR FIRST DAY ON GILENYA (CONT.)

WHAT’S NEXT

Take GILENYA on your own—
one pill, once a day.*

You can take GILENYA—with or without food—at any time of day.

REMEMBER:

Don’t skip doses. If you miss one or more doses of GILENYA, you may need to be observed by a health care professional when you take your next dose. People who stop using GILENYA may experience worsening MS symptoms and may not return to their level of function from before treatment with GILENYA. You should not stop taking GILENYA without talking with your doctor.

*GILENYA can result in a slow heart rate when first taken. You will be observed by a health care professional for at least 6 hours after you take your first dose. You may need to repeat this monitoring if you miss a dose or are a child who is moving to 0.5 mg from the 0.25 mg dose.

INDICATION

GILENYA is a prescription medicine used to treat relapsing forms of multiple sclerosis (MS) in adults and children 10 years of age and older.

IMPORTANT SAFETY INFORMATION

You should not take GILENYA if in the last 6 months you experienced heart attack, unstable angina, stroke or mini-stroke (transient ischemic attack or TIA), or certain types of heart failure. Do not take GILENYA if you have an irregular or abnormal heartbeat (arrhythmia), including a heart finding called prolonged QT as seen on an ECG, or if you take medicines that change your heart rhythm. Do not take GILENYA if you are allergic to fingolimod or any of the other ingredients.

GILENYA may cause serious side effects such as:

- Slow heart rate, especially after first dose. Adults and children will be monitored by a health care professional for at least 6 hours after the first dose or after a child takes the first dose of 0.5mg of GILENYA when switching from 0.25mg daily dose. Your pulse and blood pressure will be checked hourly. You’ll get an ECG before and 6 hours after your first dose. If any heart problems arise or your heart rate is still low, you’ll continue to be monitored. If you have any serious side effects, especially those that require treatment with other medicines, or if you have certain types of heart problems, or if you’re taking medicines that can affect your heart, you’ll be watched overnight. If you experience slow heart rate, it will usually return to normal within 1 month. Call your doctor, or seek immediate medical attention if you have any symptoms of slow heart rate, such as dizziness, tiredness, feeling like your heart is beating...
IMPORTANT SAFETY INFORMATION (CONT.)

slowly or skipping beats, or chest pain. Symptoms can happen up to 24 hours after the first dose. Call your doctor if you miss 1 or more doses of GILENYA—you may need to repeat the 6-hour monitoring.

• Increased risk of serious infections, some of which could be life threatening and cause death. You should not receive live vaccines during treatment with GILENYA and for 2 months after you stop taking GILENYA. Vaccines may not work as well when given during treatment with GILENYA. GILENYA lowers the number of white blood cells (lymphocytes) in your blood. This will usually go back to normal within 2 months of stopping GILENYA. Your doctor may do a blood test to check your white blood cells before you start GILENYA. Call your doctor right away if, while taking GILENYA or for 2 months after your last dose, you have fever, tiredness, body aches, chills, nausea, vomiting, or headache accompanied by fever, neck stiffness, sensitivity to light, nausea, and/or confusion. These may be symptoms of meningitis.

• Progressive multifocal leukoencephalopathy (PML). PML is a rare brain infection that usually leads to death or severe disability. If PML happens, it usually happens in people with weakened immune systems but has happened in people who do not have weakened immune systems. Call your doctor right away if you have any new or worsening symptoms of PML that have lasted several days, including changes in your thinking or memory, changes in your vision, decreased strength, problems with balance, weakness on 1 side of your body, loss of coordination in your arms and legs, confusion, or changes in your personality.

• Macular edema, a vision problem that can cause some of the same vision symptoms as an MS attack (optic neuritis), or no symptoms. If it happens, macular edema usually starts in the first 3 to 4 months after starting GILENYA. Your doctor should test your vision before you start GILENYA, 3 to 4 months after you start GILENYA, and any time you notice vision changes. Vision problems may continue after macular edema has gone away. Your risk of macular edema is higher if you have diabetes or have had an inflammation of your eye (uveitis). Call your doctor right away if you have blurriness, shadows, or a blind spot in the center of your vision; sensitivity to light; or unusually colored vision.

• Swelling and narrowing of the blood vessels in your brain. A condition called PRES (posterior reversible encephalopathy syndrome) has happened rarely in adults taking GILENYA. Symptoms of PRES usually get better when you stop taking GILENYA. However, if left untreated, it may lead to a stroke. Call your doctor right away if you experience any symptoms, such as sudden severe headache, sudden confusion, seizures, or sudden loss of vision.

• Breathing problems. Some patients have shortness of breath. Call your doctor right away if you have trouble breathing.

• Liver problems. Your doctor should do blood tests to check your liver before you start GILENYA. Call your doctor right away if you have nausea, vomiting, stomach pain, loss of appetite, tiredness, dark urine, or if your skin or the whites of your eyes turn yellow.
• Severe worsening of MS after stopping GILENYA. Many people who have worsening of MS symptoms after stopping GILENYA do not return to the level of function that they had before or during treatment with GILENYA. This can also occur in women stopping due to pregnancy or planning a pregnancy. This worsening happens most often within 12 weeks after stopping GILENYA, but can happen later. Do not stop taking GILENYA without talking with your doctor. Tell your doctor if you have worsening symptoms of MS after stopping GILENYA.

• Increases in blood pressure (BP). BP should be monitored during treatment.

• Cancers including basal and Merkel cell carcinoma and melanoma. Tell your doctor if you have any changes in the appearance of your skin, including changes in a mole, new darkened area in your skin, a sore that does not heal, or growths on your skin such as a bump that may be shiny, pearly white, skin colored, or pink. While taking GILENYA, limit the amount of time you spend in sunlight and ultraviolet (UV) light as well as use sunscreen with a high sun protection factor and wear protective clothing. Lymphoma has also occurred in patients receiving GILENYA.

GILENYA may harm your unborn baby. Talk to your doctor if you are pregnant or planning to become pregnant. Women who can become pregnant should use effective birth control while on GILENYA, and for at least 2 months after stopping. If you become pregnant while taking GILENYA, or within 2 months after stopping, tell your doctor right away. It is not known if GILENYA passes into breast milk. Talk to your doctor about the best way to feed your baby if you take GILENYA. A pregnancy registry is available for women who become pregnant during GILENYA treatment. For more information, contact the GILENYA Pregnancy Registry by calling Quintiles at 1-877-598-7237, by e-mailing gpr@quintiles.com, or by going to www.gilenyapregnancyregistry.com.

Tell your doctor about all your medical conditions, including if you had or now have an irregular or abnormal heartbeat; stroke or mini-stroke; heart problems; a history of repeated fainting; a fever or infection, or if you are unable to fight infections due to a disease or are taking medicines that lower your immune system, including corticosteroids, or have taken them in the past; eye problems; diabetes; breathing or liver problems; or uncontrolled high blood pressure. Also tell your doctor if you have had chicken pox or have received the chicken pox vaccine. Your doctor may test for the chicken pox virus, and you may need to get the full course of the chicken pox vaccine and wait 1 month before starting GILENYA. Children 10 years and older should complete their vaccination schedule before starting GILENYA.

If you take too much GILENYA, call your doctor or go to the nearest hospital emergency room right away.

Tell your doctor about all the medicines you take or have recently taken, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
IMPORTANT SAFETY INFORMATION (CONT.)

The most common side effects with GILENYA were headache, abnormal liver tests, diarrhea, cough, flu, sinusitis, back pain, abdominal pain, and pain in arms or legs.

In the pediatric study:

- The safety in children 10 years and older receiving GILENYA was similar to that seen in adults.
- The rate of seizures was higher in GILENYA-treated patients compared to that of a leading injectable.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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