

MEDICATION GUIDE
GILENYA® (je-LEN-yah)
(fingolimod)
capsules

Read this Medication Guide before you start using GILENYA and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your health problem or treatment.

What is the most important information I should know about GILENYA?

GILENYA may cause serious side effects, including:

1. Slow heart rate (bradycardia or bradyarrhythmia) when you start taking GILENYA.

GILENYA can cause your heart rate to slow down, especially after you take your first dose. You will have a test to check the electrical activity of your heart (ECG) before you take your first dose of GILENYA.

You will be observed by a healthcare professional for at least 6 hours after you take your first dose of GILENYA.

After you take your first dose of GILENYA:

- Your pulse and blood pressure should be checked every hour.
- You should be observed by a healthcare professional to see if you have any serious side effects. If your heart rate slows down too much, you may have symptoms such as:
 - dizziness
 - tiredness
 - feeling like your heart is beating slowly or skipping beats
- If you have any of the symptoms of slow heart rate, they will usually happen during the first 6 hours after your first dose of GILENYA. Symptoms can happen up to 24 hours after you take your first GILENYA dose.
- 6 hours after you take your first dose of GILENYA you will have another ECG. If your ECG shows any heart problems or if your heart rate is still too low or continues to decrease, you will continue to be observed.
- If you have any serious side effects after your first dose of GILENYA, especially those that require treatment with other medicines, you will stay in the medical facility to be observed overnight. You will also be observed for any serious side effects for at least 6 hours after you take your second dose of GILENYA the next day.
- If you have certain types of heart problems, or if you are taking certain types of medicines that can affect your heart, you will be observed overnight after you take your first dose of GILENYA.

Your slow heart rate will usually return to normal within 1 month after you start taking GILENYA. Call your doctor or go to the nearest hospital emergency room right away if you have any symptoms of a slow heart rate.

If you miss 1 or more doses of GILENYA you may need to be observed by a healthcare professional when you take your next dose. Call your doctor if you miss a dose of GILENYA. See **"How should I take GILENYA?"**

2. Infections. GILENYA can increase your risk of serious infections and decrease the way vaccines work in your body to prevent certain diseases, especially the chicken pox vaccine. GILENYA lowers the number of white blood cells (lymphocytes) in your blood. This will usually go back to normal within 2 months of stopping treatment. Your doctor may do a blood test before you start taking GILENYA. Call your doctor right away if you have any of these symptoms of an infection:

- fever
- tiredness
- body aches
- chills
- nausea
- vomiting
- headache accompanied by fever, neck stiffness, sensitivity to light, nausea, and/or confusion (these may be symptoms of meningitis)

3. 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. It is important that you call your doctor right away if you have any new or worsening medical problems that have lasted several days, including problems with:

- thinking
- eyesight
- strength
- balance
- weakness on 1 side of your body
- using your arms and legs

4. A problem with your vision called macular edema. Macular edema can cause some of the same vision symptoms as an MS attack (optic neuritis). You may not notice any symptoms with macular edema. If macular edema happens, it usually starts in the first 3 to 4 months after you start taking GILENYA. Your doctor should test your vision before you start taking GILENYA and 3 to 4 months after you start taking GILENYA, or any time you notice vision changes during treatment with GILENYA. Your risk of macular edema may be higher if you have diabetes or have had an inflammation of your eye called uveitis.

Call your doctor right away if you have any of the following:

- blurriness or shadows in the center of your vision
- a blind spot in the center of your vision
- sensitivity to light
- unusually colored (tinted) vision

What is GILENYA?

GILENYA is a prescription medicine used to treat relapsing forms of multiple sclerosis (MS) in adults. GILENYA can decrease the number of MS flare-ups (relapses). GILENYA does not cure MS, but it can help slow down the physical problems that MS causes.

It is not known if GILENYA is safe and effective in children under 18 years of age.

Who should not take GILENYA?

Do not take GILENYA if you:

- have had a heart attack, unstable angina, stroke or warning stroke or certain types of heart failure in the last 6 months
- have certain types of irregular or abnormal heartbeat (arrhythmia), including patients in whom a heart finding called prolonged QT is seen on ECG before starting GILENYA
- are taking certain medicines that change your heart rhythm
- are allergic (hypersensitive) to fingolimod or any of the other ingredients of GILENYA listed at the end of this medication guide. Allergic reactions, which could include symptoms of rash or itchy hives, swelling of lips, tongue or face, are more likely to occur on the day you start GILENYA treatment but may occur later. If you think you may be allergic, ask your doctor for advice.

If any of the above situations apply to you, tell your doctor.

What should I tell my doctor before taking GILENYA?

Before you take GILENYA, tell your doctor about all your medical conditions, including if you had or now have:

- an irregular or abnormal heartbeat (arrhythmia)
- a history of stroke or warning stroke
- heart problems, including heart attack or angina
- a history of repeated fainting (syncope)
- a fever or infection, or you are unable to fight infections due to a disease or taking medicines that lower your immune system. Tell your doctor if you have had chicken pox or have received the vaccine for chicken pox. Your doctor may do a blood test for chicken pox virus. You may need to get the full course of the vaccine for chicken pox and then wait 1 month before you start taking GILENYA.
- eye problems, especially an inflammation of the eye called uveitis.
- diabetes
- breathing problems, including during your sleep
- liver problems
- high blood pressure
- a type of skin cancer called basal cell carcinoma (BCC).
- Are pregnant or plan to become pregnant. GILENYA may harm your unborn baby. Talk to your doctor if you are pregnant or are planning to become pregnant.
 - Tell your doctor right away if you become pregnant while taking GILENYA or if you become pregnant within 2 months after you stop taking GILENYA.
 - If you are a female who can become pregnant, you should use effective birth control during your treatment with GILENYA and for at least 2 months after you stop taking GILENYA.

Pregnancy Registry: There is a registry for women who become pregnant during treatment with GILENYA. If you become pregnant while taking GILENYA, talk to your doctor about registering with the GILENYA Pregnancy

Registry. The purpose of this registry is to collect information about your health and your baby's health.

For more information, contact the GILENYA Pregnancy Registry by calling Quintiles at 1-877-598-7237, by sending an email to gpr@quintiles.com, or go to www.gilenyapregnancyregistry.com.

- Are breastfeeding or plan to breastfeed. It is not known if GILENYA passes into your breast milk. You and your doctor should decide if you will take GILENYA or breastfeed. You should not do both.

Tell your doctor about all the medicines you take or have recently taken, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your doctor if you take medicines that affect your immune system, including corticosteroids, or have taken them in the past.

Know the medicines you take. Keep a list of your medicines with you to show your doctor and pharmacist when you get a new medicine.

Using GILENYA and other medicines together may affect each other causing serious side effects.

Especially tell your doctor if you take vaccines. Tell your doctor if you have been vaccinated within 1 month before you start taking GILENYA. You should not get certain vaccines, called live attenuated vaccines, while you take GILENYA and for at least 2 months after you stop taking GILENYA. If you take certain vaccines, you may get the infection the vaccine should have prevented. Vaccines may not work as well when given during GILENYA treatment.

How should I take GILENYA?

- You will be observed by a healthcare professional for at least 6 hours after your first dose of GILENYA. See **"What is the most important information I should know about GILENYA?"**
- Take GILENYA exactly as your doctor tells you to take it.
- Take GILENYA 1 time each day.
- If you take too much GILENYA, call your doctor or go to the nearest hospital emergency room right away.
- Take GILENYA with or without food.
- Do not stop taking GILENYA without talking with your doctor first.
- Call your doctor right away if you miss a dose of GILENYA. You may need to be observed by a healthcare professional for at least 6 hours when you take your next dose. If you need to be observed by a healthcare professional when you take your next dose of GILENYA you will have:
 - an ECG before you take your dose
 - hourly pulse and blood pressure measurements after you take the dose
 - an ECG 6 hours after your dose
- If you have certain types of heart problems, or if you are taking certain types of medicines that can affect your heart, you will be observed overnight by a healthcare professional in a medical facility after you take your dose of GILENYA.

- If you have serious side effects after taking a dose of GILENYA, especially those that require treatment with other medicines, you will stay in the medical facility to be observed overnight. If you were observed overnight, you will also be observed for any serious side effects for at least 6 hours after you take your second dose of GILENYA. See **“What is the most important information I should know about GILENYA?”**

What are possible side effects of GILENYA?

GILENYA can cause serious side effects.

See **“What is the most important information I should know about GILENYA?”**

Serious side effects include:

- **swelling and narrowing of the blood vessels in your brain.** A condition called PRES (Posterior reversible encephalopathy syndrome) has occurred rarely in patients 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 have any of the following symptoms:
 - sudden headache
 - confusion
 - seizures
 - loss of vision
 - weakness
- **breathing problems.** Some people who take GILENYA have shortness of breath. Call your doctor right away if you have trouble breathing.
- **liver problems.** GILENYA may cause liver problems. Your doctor should do blood tests to check your liver before you start taking GILENYA. Call your doctor right away if you have any of the following symptoms of liver problems:
 - nausea
 - vomiting
 - stomach pain
 - loss of appetite
 - tiredness
 - your skin or the whites of your eyes turn yellow
 - dark urine
- **a type of skin cancer called basal cell carcinoma (BCC).** Talk to your doctor if you notice any skin nodules (e.g., shiny pearly nodules), patches or open sores that do not heal within weeks (these may be signs of BCC).

The most common side effects of GILENYA include:

- headache
- abnormal liver tests
- diarrhea
- cough
- flu
- sinusitis
- back pain

- abdominal pain
- pain in arms or legs

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of GILENYA. For more information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How do I store GILENYA?

- Store GILENYA in the original bottle or blister pack in a dry place.
- Store GILENYA at room temperature between 59°F to 86°F (15°C to 30°C).
- Keep GILENYA and all medicines out of the reach of children.

General information about GILENYA

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use GILENYA for a condition for which it was not prescribed. Do not give GILENYA to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about GILENYA. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about GILENYA that is written for healthcare professionals.

For more information, go to www.pharma.US.Novartis.com or call 1-888-669-6682.

What are the ingredients in GILENYA?

Active ingredient: fingolimod

Inactive ingredients: gelatin, magnesium stearate, mannitol, titanium dioxide, yellow iron oxide.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

GILENYA is a registered trademark of Novartis AG.

Manufactured by:
Novartis Pharma Stein AG
Stein, Switzerland

Distributed by:
Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936

© Novartis

T2016-23
Revised: February 2016