

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 medical condition or your 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 the first dose. Your heart rate will usually slow down the most about 6 hours after you take your first dose of GILENYA. You might feel dizzy or tired or be aware of a slow or irregular heartbeat if your heart rate slows down. Usually, if you experience these types of symptoms due to the slowing down of your heart rate, they will occur during the first 6 hours after the first dose. Your doctor will watch you for the first 6 hours after you take the first dose to see if you have any serious side effects. Your slow heart rate will usually return to normal within 1 month after you start taking GILENYA.

Call your doctor if at any time you have:

- dizziness
- tiredness
- a slow or irregular heartbeat

2. Infections. GILENYA can increase your risk of serious infections. 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

3. 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. Macular edema 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 age 18.

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 heart rate less than 55 beats a minute
- heart problems
- a history of fainting (syncope)
- a fever or infection, or you are unable to fight infections. 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 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
- liver problems
- high blood pressure
- 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, you can call the GILENYA Pregnancy Registry at 1-877-598-7237.

- 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, including prescription and non-prescription medicines, vitamins, and herbal supplements.

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:

- Medicines for heart problems or high blood pressure
- Vaccines. Tell your doctor if you have been vaccinated within 1 month before you start taking GILENYA. You should not get certain 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.
- Medicines that could raise your chance of getting infections, such as medicines to treat cancer or to control your immune system.
- ketoconazole (an antifungal drug) by mouth

Ask your doctor or pharmacist for a list of these medicines if you are not sure.

How should I take GILENYA?

- Your first dose of GILENYA will be given in a doctor's office or clinic, where you will be observed for 6 hours after your first dose of GILENYA.
- Take GILENYA exactly as your doctor tells you to take it.
- Take GILENYA 1 time each day.
- Take GILENYA with or without food.
- Do not stop taking GILENYA without talking with your doctor first.
- If you start GILENYA again after stopping for 2 weeks or more, you will start taking GILENYA again in your doctor's office or clinic.

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:

- **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

The most common side effects of GILENYA include:

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

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 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 trademark of Novartis AG.

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