MEDICATION GUIDE
GILENYA® (je-LEN-yah)
(fingolimod)
capsules, for oral use

Read this Medication Guide before you start taking GILENYA and each time you get a refill. There may be new information. If you are the parent of a child who is being treated with GILENYA, the following information applies to your child. This information does not take the place of talking to your healthcare provider 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 your first dose. You will have a test, called an electrocardiogram (ECG), to check the electrical activity of your heart before you take your first dose of GILENYA.

   All adults and children will be observed by a healthcare professional for at least 6 hours after taking their first dose of GILENYA. Children should also be observed by a healthcare professional for at least 6 hours after taking their first dose of 0.5 mg of GILENYA when switching from the 0.25 mg dose.

   After you take your first dose of GILENYA, and after a child takes their first dose of 0.5 mg of GILENYA when switching from the 0.25 mg dose:

   - 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
     - chest pain
   - 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 healthcare provider 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 healthcare provider if you miss a dose of GILENYA. See **"How should I take GILENYA?"**

2. **Pregnancy.** Please consult your healthcare provider before getting pregnant. You should avoid becoming pregnant while taking GILENYA or in the two months after you stop taking it because of the risk of harm to the baby.

3. **Infections.** GILENYA can increase your risk of serious infections that can 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. Talk to your healthcare provider before you receive a vaccine during treatment and for 2 months after treatment with GILENYA. If you receive a live vaccine, you may get the infection the vaccine was meant to prevent. Vaccines may not work as well when given during treatment with GILENYA.

   Human Papilloma Virus (HPV). Due to risk of HPV infection please consult your healthcare provider for routine pap smear.

   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 healthcare provider may do a blood test to check your white

blood cells before you start taking GILENYA. Call your healthcare provider right away if you have any of these symptoms of an infection during treatment with GILENYA, and for 2 months after your last dose of GILENYA:

- fever
- tiredness
- body aches
- chills
- nausea
- vomiting
- headache with fever, neck stiffness, sensitivity to light, nausea, or confusion (these may be symptoms of meningitis, an infection of the lining around your brain and spine)

4. **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. Symptoms of PML get worse over days to weeks. Call your healthcare provider right away if you have any new or worsening symptoms of PML, that have lasted several days, including:
   - weakness on 1 side of your body
   - loss of coordination in your arms and legs
   - decreased strength
   - problems with balance
   - changes in your vision
   - changes in your thinking or memory
   - confusion
   - changes in your personality
5. **A problem with your vision called macular edema.** Macular edema can cause some of the same vision symptoms as a multiple sclerosis (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 but can happen at any time. Your healthcare provider should test your vision around the time you start taking GILENYA, 3 to 4 months after you start taking GILENYA, periodically while you continue taking GILENYA, and any time you notice vision changes during treatment with GILENYA. Your risk of macular edema is higher if you have diabetes or have had an inflammation of your eye called uveitis.

   Call your healthcare provider right away if you have any of the following symptoms:
   - 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), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults and children 10 years of age and older.

It is not known if GILENYA is safe and effective in children under 10 years of age.

Who should not take GILENYA?

Do not take GILENYA if you:

- have had a heart attack, unstable angina, stroke, or mini stroke (transient ischemic attack or TIA) 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.
- have a heart rhythm problem that needs treatment with certain medicines.
- are allergic to fingolimod or any of the ingredients in GILENYA. See the end of this leaflet for a complete list of ingredients in GILENYA. Symptoms of an allergic reaction may include: rash, itchy hives, or swelling of the lips, tongue or face.

Talk to your healthcare provider before taking GILENYA if you have any of these conditions, or do not know if you have any of these conditions.

What should I tell my healthcare provider before taking GILENYA?

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

- an irregular or abnormal heartbeat (arrhythmia).
- a history of stroke or mini 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 take or have taken medicines that lower your immune system.
- recently received a vaccine or are scheduled to receive a vaccine.

- chickenpox or have received the vaccine for chickenpox. Your healthcare provider may do a blood test for chickenpox virus. You may need to get the full course of the vaccine for chickenpox and then wait 1 month before you start taking GILENYA.
- your child has completed their vaccination schedule. Your child needs to have completed their vaccination schedule before starting treatment with GILENYA.
- eye problems, especially an inflammation of the eye called uveitis.
- diabetes.
- breathing problems, including during your sleep.
- liver problems.
- high blood pressure.
- any type of skin cancer, including basal cell carcinoma (BCC), melanoma, or squamous cell carcinoma (SCC).
- are pregnant or plan to become pregnant. GILENYA may harm your unborn baby. Talk to your healthcare provider if you are pregnant or are planning to become pregnant. Tell your healthcare provider right away if you become pregnant while taking GILENYA or if you become pregnant within 2 months after you stop taking GILENYA.
  - You should stop taking GILENYA 2 months before trying to become pregnant.
  - 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.
- are breastfeeding or plan to breastfeed. It is not known if GILENYA passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take GILENYA.

Tell your healthcare provider about all the medicines you take or have recently taken, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Especially tell your healthcare provider 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 healthcare provider and pharmacist when you get a new medicine.

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

How should I take GILENYA?

- Adults and children will be observed by a healthcare professional for at least 6 hours after taking their first dose of GILENYA. **Children should also be observed by a healthcare professional for at least 6 hours after taking their first dose of 0.5 mg of GILENYA when switching from the 0.25 mg dose.** See **"What is the most important information I should know about GILENYA?"**
- Take GILENYA exactly as your healthcare provider tells you to take it.
- Take GILENYA 1 time each day.
- If you take too much GILENYA, call your healthcare provider 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 healthcare provider first.
- Call your healthcare provider 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, including:

- See **"What is the most important information I should know about GILENYA?"**
- **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 healthcare provider right away if you have any of the following symptoms:
  - sudden severe headache
  - sudden confusion
  - sudden loss of vision or other changes in your vision
  - seizure
- **liver damage.** GILENYA may cause liver damage. Your healthcare provider should do blood tests to check your liver before you start taking GILENYA and periodically during treatment. Call your healthcare provider right away if you have any of the following symptoms of liver damage:
  - nausea
  - vomiting
  - stomach pain
  - tiredness
  - loss of appetite
  - your skin or the whites of your eyes turn yellow
  - dark urine
- **breathing problems.** Some people who take GILENYA have shortness of breath. Call your healthcare provider right away if you have new or worsening breathing problems.
- **severe worsening of multiple sclerosis after stopping GILENYA.** When GILENYA is stopped, symptoms of MS can return and become worse compared to before or during treatment. Many people who have worsening of MS symptoms after stopping GILENYA do not return to the level of function that they had before stopping GILENYA. This worsening happens most often within 12 weeks after stopping GILENYA but can happen later. Always talk to your healthcare provider before you stop taking GILENYA for any reason. Tell your healthcare provider if you have worsening symptoms of MS after stopping GILENYA.
- **increased blood pressure.** Your healthcare provider should check your blood pressure during treatment with GILENYA.
- **types of skin cancer, including basal cell carcinoma, melanoma, and squamous cell carcinoma.** Tell your healthcare provider if you have any changes in the appearance of your skin, including changes in a mole, a new darkened area on 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. Your healthcare provider should check your skin for any changes at the start of and during treatment with GILENYA. Limit the amount of time you spend in sunlight and ultraviolet (UV) light. Wear protective clothing and use a sunscreen with a high sun protection factor.
- **allergic reactions.** Call your healthcare provider if you have symptoms of an allergic reaction, including a rash, itchy hives, or swelling of the lips, tongue or face.

The most common side effects of GILENYA include:

- headache
- abnormal liver tests
- diarrhea
- cough
- flu
- inflammation of the sinuses (sinusitis)
- back pain
- stomach-area (abdominal) pain
- pain in arms or legs

Tell your healthcare provider 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 healthcare provider or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store GILENYA?

- Store GILENYA in the original bottle or blister pack in a dry place.
- Store GILENYA at room temperature between 68°F to 77°F (20°C to 25°C).
- **Keep GILENYA and all medicines out of the reach of children.**

General information about the safe and effective use of 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 that 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 healthcare provider. You can ask your healthcare provider or pharmacist for information about GILENYA that is written for health professionals.

What are the ingredients in GILENYA?

0.25 mg capsules
Active ingredient: fingolimod
Inactive ingredients: gelatin, hydroxypropylbetadex, hydroxypropylcellulose, magnesium stearate, mannitol, titanium dioxide, yellow iron oxide.

0.5 mg capsules
Active ingredient: fingolimod hydrochloride
Inactive ingredients: gelatin, magnesium stearate, mannitol, titanium dioxide, yellow iron oxide.

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

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This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised: August 2025
T2025-54