GILENYA@Home

Get patients started on GILENYA with a flexible new option*—just submit an SRF and let us take care of the rest

*Limitations apply.

Not an actual patient.

Indication

GILENYA is a sphingosine 1-phosphate receptor modulator indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS) to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability.

Important Safety Information

Contraindications

- Patients who in the last 6 months experienced myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure (HF) requiring hospitalization or Class III/IV HF
- History or presence of Mobitz Type II second-degree or third-degree atrioventricular (AV) block or sick sinus syndrome, unless patient has a functioning pacemaker
- Baseline QTc interval ≥500 msec
- Treatment with Class Ia or Class III anti-arrhythmic drugs

Please see additional Important Safety Information on following pages.
Please see accompanying full Prescribing Information.

GILENYA™
(fingolimod) capsules 0.5 mg

Experience the Power

What is GILENYA@Home?

The baseline assessments and/or first-dose observation (FDO) for GILENYA can now be conducted from the comfort of home for patients with commercial insurance.[*] A completed SRF is all that's required to get eligible patients started.

GILENYA@Home baseline assessments and FDO:

- Are performed in familiar surroundings
- Are covered at no additional cost to your patients with commercial insurance[†]
- Remove the inconvenience of travel
- Are arranged at a time that is convenient to your patients, including weekends

The GILENYA@Home medical professional(s):

- Review your patient's medical history and medications
- Conduct baseline assessments, if requested
- Perform the FDO and monitor the patient — the medical team will be on-site for the duration of the FDO, checking the patient's blood pressure and pulse hourly
- Send a full test report to your practice within 24 hours
- Have the resources to manage adverse events
- Can facilitate extended observation up to 10 hours, if required

[*]The eye exam is available in select GILENYA@Home markets.
[†]Patients using Medicare, Medicaid, TRICARE, or patients who reside in Massachusetts, Michigan, or Rhode Island are not eligible for services sponsored by Novartis. Other limitations apply.

Important Safety Information (continued)

Bradyarrhythmia and AV Block: Monitor patients during GILENYA initiation because of a risk of bradyarrhythmia and AV block. Observe all patients for signs and symptoms of bradycardia for at least 6 hours after first dose with hourly pulse and blood pressure (BP) measurement. Obtain an electrocardiogram (ECG) prior to dosing and at the end of the observation period. Patients who develop a heart rate (HR) <45 bpm or new onset second degree or higher AV block should be monitored until resolution. Patients at lowest post-dose HR at end of observation period should be monitored until HR increases. Begin continuous ECG monitoring in patients with symptomatic bradycardia, and if pharmacological intervention is needed, continue ECG monitoring overnight in a medical facility, and repeat first-dose monitoring for second dose. Some patients may experience a second decrease in HR within 24 hours after the first dose. Patients with pre-existing ischemic heart disease, history of MI or cardiac arrest, CHF, cerebrovascular disease, uncontrolled hypertension, history of symptomatic bradycardia or recurrent syncope, severe untreated sleep apnea, AV block, sinoatrial heart block, and patients on concomitant drugs that slow HR or AV conduction should be evaluated by a physician and, if treated with GILENYA, monitored overnight with continuous ECG in a medical facility after the first dose due to higher risk of symptomatic bradycardia or heart block. Patients with or at risk for QT prolongation or on concomitant QT-prolonging drugs with a known risk of torsades de pointes should also be monitored overnight with continuous ECG. If GILENYA is discontinued for >14 days after the first month of treatment, the effects on HR and AV conduction may recur on reintroduction of treatment and the same precautions for initial dosing should apply. Take the same precautions if treatment is interrupted ≥1 day within the first 2 weeks or for >7 days during weeks 3 and 4.

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GILENYA@Home FAQs

Who is providing the GILENYA@Home service?

Novartis has partnered with Visiting Physicians Association (VPA), the nation's leader in the field of home care. For 20 years, VPA has delivered more than 950,000 in-home medical encounters annually.

Who performs the GILENYA@Home FDO?

An experienced health care professional, such as a physician or NP/PA, and a medical assistant will perform the FDO and monitor your patient.

Can baseline assessments also be performed in-home?

Yes. Prior to the in-home FDO, baseline assessments can be performed.[*] Baseline ECGs can be performed and read on-site the day of the observation. The eye exam is available in select GILENYA@Home markets.

What do my patients do during the GILENYA@Home FDO?

During the observation period, patients may engage in normal daily activity, but must remain at home. Heavy physical activity is discouraged during this time.

What happens if extended monitoring is necessary?

The on-site medical team will monitor the patient for up to 10 hours: 6 hours for the FDO and 4 hours if extended monitoring is necessary. If monitoring is required beyond this, the patient will be transported to a medical facility.

To learn more about GILENYA@Home, or to set up an appointment for your patient, contact your Novartis representative or call 1-800-445-3692.

Important Safety Information (continued)

Infections: GILENYA may increase the risk of infections. A recent CBC should be available before initiating GILENYA. Consider suspending GILENYA if a patient develops a serious infection. Monitor for signs and symptoms of infection during treatment and up to 2 months after discontinuation. Do not start GILENYA in patients with active acute or chronic infections. Two patients receiving a higher dose of GILENYA (1.25 mg) in conjunction with high-dose corticosteroid therapy died of herpetic infections. Cryptococcal infections, including cases of cryptococcal meningitis, have been reported with GILENYA in the postmarketing setting. Patients with symptoms and signs consistent with cryptococcal meningitis should undergo prompt diagnostic evaluation and treatment. Concomitant use with antineoplastic, immunosuppressive, or immune-modulating therapies would be expected to increase the risk of immunosuppression. To avoid additive immunosuppressive effects, consider the duration of effect and mode of action of such therapies. Before initiating GILENYA, patients without a history of chickenpox or without vaccination against varicella zoster virus (VZV) should be tested for antibodies to VZV. VZV vaccination of antibody-negative patients is recommended prior to commencing GILENYA treatment, following which GILENYA initiation should be postponed for 1 month.

Please see additional Important Safety Information on previous and following pages.
Please see accompanying full Prescribing Information.

Important Safety Information (continued)

Progressive Multifocal Leukoencephalopathy: A case of progressive multifocal leukoencephalopathy (PML) and a case of probable PML occurred in patients with MS who received GILENYA in the postmarketing setting. PML is an opportunistic viral infection of the brain caused by the JC virus (JCV) that typically only occurs in patients who are immunocompromised, and that usually leads to death or severe disability.

Typical symptoms associated with PML are diverse, progress over days to weeks, and include progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes. MRI signs may be apparent before clinical symptoms.

At the first sign or symptom suggestive of PML, withhold GILENYA and perform an appropriate diagnostic evaluation.

Macular Edema: Fingolimod increases the risk of macular edema, with or without visual symptoms. Perform an exam of the fundus, including the macula, before starting GILENYA and at 3 to 4 months after initiation. Monitor visual acuity at baseline and during routine patient evaluations. Patients with diabetes mellitus or history of uveitis are at increased risk and should have regular ophthalmologic evaluations.

Posterior Reversible Encephalopathy Syndrome (PRES): Rare cases of PRES have been reported with GILENYA. Symptoms reported included sudden onset of severe headache, altered mental status, visual disturbances, and seizure. Symptoms of PRES are usually reversible but may evolve into ischemic stroke or cerebral hemorrhage. Delay in diagnosis and treatment may lead to permanent neurological sequelae. If PRES is suspected, GILENYA should be discontinued.

Respiratory Effects: Dose-dependent reductions in forced expiratory volume over 1 second (FEV1) and diffusion lung capacity for carbon monoxide (DLCO) were observed in GILENYA patients as early as 1 month after initiation. The changes in FEV1 appear to be reversible after discontinuing GILENYA; however, there is insufficient information to determine the reversibility of DLCO. Obtain spirometry and DLCO when clinically indicated.

Liver Injury: Recent liver transaminase and bilirubin levels should be available before initiating GILENYA. Elevations 3- and 5-fold the upper limit of normal have occurred with GILENYA. The majority occurred within 6 to 9 months and returned to normal within 2 months after discontinuing GILENYA. Recurrence of liver transaminase elevations occurred with rechallenge in some patients. Assess liver enzymes if symptoms suggestive of hepatic injury develop. Discontinue GILENYA if significant liver injury is confirmed.

Fetal Risk: GILENYA may cause fetal harm. Women of childbearing potential should use effective contraception during and for 2 months after stopping GILENYA. A registry for women who become pregnant during GILENYA treatment is available. Contact the GILENYA Pregnancy Registry by calling OUTCOME at 1-877-598-7237, sending an e-mail to gpr@outcome.com, or accessing gilenyapregnancyregistry.com.

Blood Pressure Effects: BP should be monitored during treatment with GILENYA. An average increase over placebo of 3 mm Hg in systolic and 2 mm Hg in diastolic BP was observed in clinical trials.

Immune System Effects Following Discontinuation: Fingolimod remains in the blood and has pharmacodynamic effects, including decreased lymphocyte counts, for up to 2 months following the last dose. Lymphocyte counts generally return to normal range within 1 to 2 months of stopping therapy. Initiating other drugs during this period warrants the same considerations needed for concomitant administration.

Drug Interactions: Closely monitor patients receiving systemic ketoconazole. The use of live attenuated vaccines should be avoided during and for 2 months after stopping GILENYA.

Common Adverse Reactions: The most common adverse reactions with GILENYA (incidence ≥10% and >placebo) compared with placebo were headache, liver transaminase elevations, diarrhea, cough, influenza, sinusitis, back pain, abdominal pain, and pain in extremity.

Please see additional Important Safety Information on previous pages.
Please see accompanying full Prescribing Information.

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