

# Gilenya<sup>®</sup> (Jil-EN-ee-ah)

Generic name: fingolimod (fin **gole** i mod)

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## What is Gilenya<sup>®</sup>?

Gilenya<sup>®</sup> is a medication that easily enters the bloodstream when taken orally. It binds to a protein called sphingosine 1-phosphate receptor (S1PR).

The S1PR is a protein that is found on the surface of many cells. There are five types of S1PR located on different types of cells in the body, and Gilenya<sup>®</sup> blocks four of these types. One of the types of S1PR that Gilenya<sup>®</sup> blocks is found on lymphocytes. Lymphocytes are believed to be responsible for the immune attack on the nervous system that causes multiple sclerosis. Lymphocytes circulate around the body in the blood. They eventually lodge in a lymph node which they must navigate through to exit back into the bloodstream. In the lymph node, potential targets are presented to lymphocytes. These lymphocytes can be activated by these targets and can attack the targets once they reenter the bloodstream. If lymphocytes are directed against inappropriate targets, like the body's own proteins, they are killed in the lymph node. The S1PR is key to directing the navigation of lymphocytes through the lymph node. When S1PR is bound by Gilenya<sup>®</sup>, lymphocytes stay in the lymph node longer resulting in more opportunities to be eliminated if they are directed against inappropriate targets. Since lymphocytes do not live very long, many also die in the lymph nodes resulting in fewer in the bloodstream. This results in a decrease in blood levels of lymphocytes that contribute to the immune attack on the nervous system in multiple sclerosis.

Oligodendrocytes are the cells that make myelin in the nervous system. Oligodendrocyte precursors are cells that are capable of reproducing and making more mature oligodendrocytes. These cells also have S1PR receptors that Gilenya<sup>®</sup> binds. This causes these cells to reproduce. Thus, Gilenya<sup>®</sup> may have a role in promoting repair of myelin. This possible role for Gilenya<sup>®</sup> has not been proven in humans.

Gilenya<sup>®</sup> slows the course of multiple sclerosis when used regularly over long periods of time. It does not improve existing symptoms and is not used to treat acute MS attacks.

## Starting on Gilenya<sup>®</sup>.

To obtain Gilenya<sup>®</sup>, a form must be completed and faxed to the Gilenya<sup>®</sup> support program. This program, operated by Novartis (the manufacturer of Gilenya<sup>®</sup>), will start the process of obtaining the medication. The MS Center staff will assist with completion of these forms and getting insurance approval. It takes about 10-14 days to get insurance approval. The first dose of medication is then shipped to the MS Center. There are also several tests that must be obtained prior to starting the medication. These are:

- Blood tests for basic liver, kidney and blood functions



## Multiple Sclerosis Center

1600 East Jefferson St., Suite A  
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[www.swedish.org/ms](http://www.swedish.org/ms) or  
[www.swedishmscenter.org](http://www.swedishmscenter.org)

- Blood tests to assure adequate immunity to chickenpox (varicella). If the immunity to chickenpox is not adequate, then patients are vaccinated. We then wait at least 30 days before sending another blood test for immunity to chickenpox. Gilenya<sup>®</sup> can be started when immunity is adequate.
- A baseline eye examination.
- An electrocardiogram (ECGs, EKGs, heart tracings)
- A test of pulmonary function is performed if patients have prior lung disease.
- A baseline MRI is usually obtained prior to starting a new disease-modifying treatment.

After the medication arrives, you will be contacted for an appointment to receive your first dose. Patients arrive at 8AM at the MS Center for their first dose. They may walk around the clinic, but must stay in the Center for six hours of blood pressure and pulse monitoring. Patients should bring activities to keep themselves entertained during the monitoring. Wireless internet access and computers are available for patient use during the monitoring. Electrocardiograms are done before scheduling the first dose observation. They are also done before and after the six hours of monitoring on the first dose observation. On the day of the first dose, patients must remain under observation until their heart rate starts increasing. Rarely, patients must be admitted to the hospital if their pulse has not started to increase by the close of clinic. Starting on the second day, patients can safely take the medication on their own at home.

Gilenya<sup>®</sup> is started at full dose without a taper.

### **How should Gilenya<sup>®</sup> be taken?**

Gilenya<sup>®</sup> is taken orally

Dose: 0.5mg

Frequency: once a day

Laboratory tests are needed when starting this medication, but are not required long term

### **What if a dose is missed?**

Take the next dose if you are 8 hours late or less. If you are more than 8 hours late on the dose, then skip that dose and take your Gilenya<sup>®</sup> at your regular time the following day.

**How should Gilenya<sup>®</sup> be stored?** This medication should be stored at room temperature, between 59 and 86.

**How supplied:** Gilenya<sup>®</sup> is supplied in packs containing either 7 or 28 pills each. Depending on insurance requirements, 4 or 12 weeks are usually shipped to patients each time.

### **What are the common side effects?**



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- **Slow heart rate:** Gilenya<sup>®</sup> can slow the heart rate after the first dose. This is the reason that the first dose must be given in the clinic. This is seen in less than 2% of patients. About 0.5% will get symptoms of a slow heart rate including dizziness, lightheadedness, fatigue, palpitations (feeling the heart skip beats) or chest pain. These usually respond to physical activity to raise the heart rate, or to lying flat with the legs elevated. The slow heart rate develops over several hours, and begins to reverse by six hours. The slowest heart rates are seen on the first day. The heart rate can fall during other days, but not at much as on the first day. By 30 days there is no effect on the heart rate.

During the first two weeks after starting treatment, the first dose observation must be repeated if Gilenya<sup>®</sup> is missed for one or more days. During the third and fourth weeks after starting treatment, the first dose observation must be repeated if Gilenya<sup>®</sup> is missed for seven or more days. After the first four weeks, the first dose observation must be repeated if Gilenya<sup>®</sup> is missed for 14 or more days.

- **Macular edema:** Macular edema is swelling of the retina in the back of the eye. This is seen in 0.4% of people receiving Gilenya<sup>®</sup> and it generally occurs within the first few months of starting the medication. Most people with macular edema have no symptoms, but about 1/3 of the 0.4% notice blurring of vision. Other symptoms include shadows or a blind spot in the center of vision, sensitivity to light or tinted vision. Macular edema usually goes away without treatment.

An ophthalmology examination is done before starting Gilenya<sup>®</sup> and 3-4 months later. This examination usually includes a special test called an ocular coherence tomography (OCT). This test is painless, takes a few minutes per eye, and uses a light beam to measure the thickness of the retina.

- **Lymphocyte counts:** Lymphocytes are a type of white blood cell. The levels of lymphocytes in the blood may have marked decreases. However, even patients with severe decreases in lymphocytes associated with Gilenya<sup>®</sup> are not considered to be immunosuppressed and are not at risk of infections. This low lymphocyte count is expected with the medication and is not a cause for alarm. In general, monitoring of lymphocytes is not recommended with this medication.
- **Infection:** In general, there is not an increase in infections with Gilenya<sup>®</sup> except for bronchitis which was seen in 8% of those taking the medication compared to 4% in those given a placebo. Though there is not an increase in any other infection, care is taken to assure that patients receiving Gilenya<sup>®</sup> are immune to chicken pox since it can cause serious infections in adults who are not immune to the virus. Immunity to chicken pox can fade after several years, so having a history of chickenpox does not assure immunity. This requires a blood test prior to starting Gilenya<sup>®</sup>, and those with inadequate immunity



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to this virus are vaccinated for chickenpox before starting the medication.

- Pulmonary function: Gilenya<sup>®</sup> may cause a slight fall in pulmonary function. In a measure of how much air a patient could blow out in one second, those treated with Gilenya<sup>®</sup> fell 3.1% compared to 2% for placebo over 2 years. In a measure of oxygen absorption, those treated with Gilenya<sup>®</sup> fell 3.8% compared to 2.7% for placebo. There was no difference between the Gilenya<sup>®</sup> and placebo groups in breathing symptoms.

Pulmonary function tests are obtained prior to starting the medication in patients with suspected lung disease. These tests may be obtained during treatment if patients develop lung symptoms.

- Liver function: Changes in liver function were found in 14% of those treated with Gilenya<sup>®</sup> compared to 5% in the placebo group. These changes did not cause any symptoms and they returned to normal if the medication was stopped. In those cases where the medication was not stopped, the liver function still returned to normal.

Liver function is measured by a blood test before starting Gilenya<sup>®</sup>. Liver function should be measured again if symptoms of liver damage occur such as jaundice (skin or white of eyes turn yellow), persistent dark urine, prolonged nausea or vomiting, stomach pain, loss of appetite or unexplained fatigue.

- Blood pressure: In those taking Gilenya<sup>®</sup> the blood pressure increased slightly. Systolic pressure (the top number on a blood pressure reading) increased an average of 2 mmHg. Diastolic pressure (the bottom number on a blood pressure reading) increased an average of 1 mmHg. This effect was seen by 2 months on the medication. Blood pressures are measured during regular clinic visits.
- Diarrhea: There was a slight increase in diarrhea which was seen in 11.8% of those on Gilenya<sup>®</sup> and 7.4% of those on placebo.

**Company Support:**

The Gilenya<sup>®</sup> Support Program 1-877-408-4974 provides financial assistance, insurance assistance, information about Gilenya<sup>®</sup> and multiple sclerosis.

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