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MS Treatments

# MSology Essentials Series

**Gilenya<sup>®</sup>**  
(fingolimod)

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## Why treat MS?

Multiple sclerosis (MS) is believed to be caused by an abnormal immune response, which results in inflammation and tissue damage in the brain and spinal cord (together called the central nervous system, or CNS). This inflammation is the cause of MS symptoms, such as nerve tingling, muscle weakness, vision problems, balance difficulties and pain. New or worsening MS symptoms that last for more than a day or two are called relapses, and these generally indicate an inflammatory flare-up in the CNS. Relapse symptoms can persist for several weeks or months. Some relapses will resolve completely and some will not. As you experience more and more relapses, the body is unable to repair the damage to the brain and spinal cord, which typically leads to physical and mental impairments.

That is why it is so important to treat MS – to reduce inflammation and tissue damage, and reduce or delay disability. The medications prescribed are called disease-modifying therapies because they target the underlying MS disease process. They do not heal any tissue damage that has already occurred, but they may prevent further damage that will contribute to disability in the years ahead.

MS medications do not treat specific symptoms, so you will not feel an improvement in the symptoms you are having. The main effects of therapy are to lessen the frequency and severity of relapses, and reduce the amount of inflammation in the brain and spinal cord. So treatment can be seen as an investment in your future – lessening the often silent damage that is occurring now to prevent disabilities later on.



## How does Gilenya work?

Gilenya is an oral medication (capsule) used to treat relapsing-remitting multiple sclerosis.

In MS, specialized cells of the immune system become activated, enter the CNS and cause inflammation and tissue damage. Gilenya is able to lock away these immune cells in the lymph nodes so they aren't able to get into the CNS and cause damage.

Clinical trials of Gilenya have shown that it reduces the rate of relapses, delays the onset of worsening disability, and suppresses inflammatory lesions in the brain in people with MS.

## Starting Gilenya

Gilenya can lower your heart rate (pulse) and blood pressure when you start the medication, so you must be monitored when you take your first-dose. An appointment will be scheduled for you to go to a first-dose clinic. The first-dose observation takes 6 hours, so you'll need to book off time from work or school. When you arrive at the clinic, a nurse will ask you about your medical history and check your pulse and blood pressure.



**You must take the first dose of Gilenya at a clinic. This appointment takes at least 6 hours, so pack a lunch, and bring a book or some work to do to keep yourself busy.**



An electrocardiogram (ECG) will be performed before and after you take your first dose, and your pulse and blood pressure will be checked periodically to ensure that everything is fine. You may need to stay longer if the test results are abnormal. It's best not to drive after your first dose, so arrange to have someone take you home.

After taking the first dose, Gilenya can be taken at home like other medications.

It's always important to take every dose of your medication as prescribed by your doctor so you receive the full benefit of treatment. This is especially important during the first 4 weeks of taking Gilenya: if you forget to take too many doses, you will need to go back to the clinic for another 6-hour appointment. This can be avoided simply by remembering to take your Gilenya once a day.



## How do I take Gilenya?

### Dosing

Gilenya must be taken once a day.

**1x**  
a day

Gilenya is a capsule (0.5 mg), to be taken by mouth, without chewing.

  
**0.5 mg**

Gilenya may be taken with or without food.



### Considerations

Try to get into a routine of taking it at the same time each day, such as with breakfast or with your evening meal.



If you forget to take a dose, do not double up the dose. Take your pill as soon as you remember (e.g. at lunch if you forgot at breakfast) or when you would normally take the next dose (e.g. at breakfast).





## How do I know my treatment is working?

During your course of treatment, your doctor will monitor your response to treatment with a variety of tests and procedures. These typically include neurological examinations to evaluate your nerve and muscle function, and magnetic resonance imaging (MRI) to assess the extent of inflammatory activity in your brain and spinal cord. Other tests and procedures may also be needed during your course of treatment.

## What if I have a relapse?

A *relapse* is a new MS symptom you haven't had before, or a worsening of symptoms you've previously experienced. The symptom persists for at least 24 hours. If you become overheated – from exercise, a hot bath, a fever or infection – your MS can worsen for a shorter period of time, but these symptoms are not a true relapse.

You may have a relapse in the first few months after starting treatment, especially if your MS was very active before. This doesn't mean your medication is not working. You will only experience the full benefit of your MS medication after you've been taking it continuously for a few months.

It's important to inform your neurologist or MS nurse if you experience a relapse or any new or worsening symptoms that last more than 24 hours.



## What are the possible side effects of Gilenya?

### Effects on the heart

The first dose of Gilenya may slightly slow your heart rate (pulse) and lower blood pressure. These can occasionally cause symptoms such as dizziness or palpitations and, more rarely, effects on the heart rhythm. So your heart function will be monitored at the first-dose clinic. After a week or so, your body gets used to treatment and these heart effects typically go away. Gilenya can cause small increases in blood pressure later on, so your doctor will need to measure your blood pressure from time to time.

### Headaches

If you experience headaches, take a pain reliever (e.g. Aspirin, Tylenol, ibuprofen) as you would for other headaches.

### Infections

You may be more susceptible to infections during treatment. Contact your doctor or MS clinic nurse immediately if you think you have an infection. If you have not been exposed to chickenpox (varicella zoster virus) before, you'll need to be vaccinated before starting Gilenya.





## Blurred vision

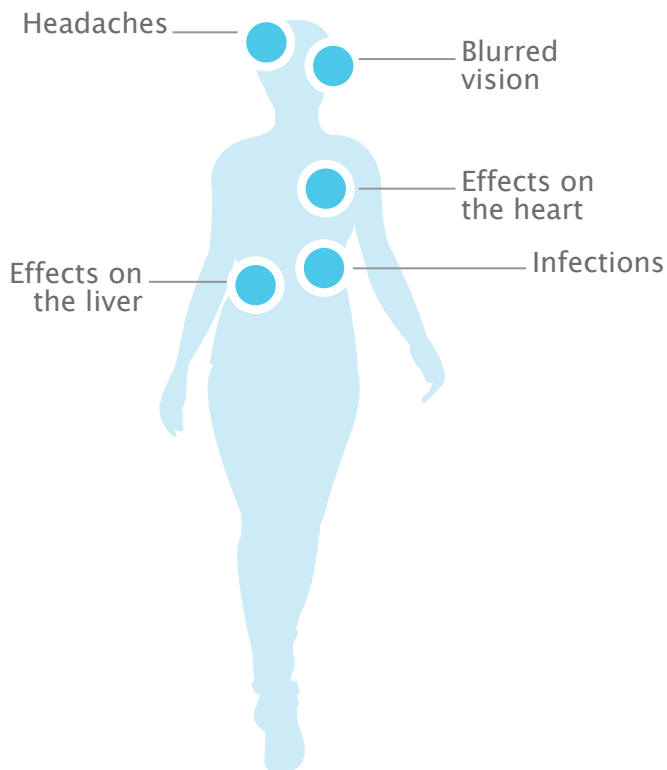
Gilenya can cause swelling inside the eye and you will need to have an eye exam once you've been on treatment for a few months. Eye symptoms may also be due to your MS, so contact your doctor or MS nurse if you are having any new or worsening vision problems.

## Effects on the liver

Gilenya can have an effect on liver function so regular blood tests are needed. Report any symptoms of liver problems to your doctor immediately. These symptoms may include unexplained nausea/vomiting, abdominal pain, dark urine, yellowing of the skin (jaundice), loss of appetite and unusual tiredness.

## PML

One case of PML (progressive multifocal leukoencephalopathy), a potentially fatal brain infection, has been reported with Gilenya. The risk of PML is considered to be very low.



All medications have the potential to cause a variety of side effects. If you experience any new, unusual or worrisome symptoms while taking your medication, report them promptly to your doctor or MS nurse. Your MS nurse can often provide helpful advice to minimize any unwanted medication-related effects you may experience.



## Tests and procedures

During your course of treatment, your doctor will order a number of tests to ensure that your medication is not causing any unwanted effects. Some of the suggested tests are listed in the table. However, your neurologist and MS nurse will schedule which tests you will need and how often they should be done.

### Tests you may need during treatment with Gilenya\*

Test/procedure	Reason	How often
Antibody test** (blood test)	To see if you have had prior exposure to chickenpox	<ul style="list-style-type: none"><li>• Before starting Gilenya</li></ul>
Vaccination**	To ensure immunity against chickenpox (varicella zoster virus)	<ul style="list-style-type: none"><li>• Before starting Gilenya</li></ul>
First dose monitoring: – Pulse – ECG (electrocardiogram) – Blood pressure	To monitor heart function	<ul style="list-style-type: none"><li>• During the first-dose clinic</li><li>• Blood pressure should be checked periodically according to your physician</li></ul>
Blood test	To determine your complete blood cell count (CBC)  The blood test will also be used to assess your liver function	<ul style="list-style-type: none"><li>• Before starting Gilenya</li><li>• Every 3–6 months in the first year of treatment</li><li>• Periodically according to your physician</li></ul>
Eye exam	To check for swelling in the eye	<ul style="list-style-type: none"><li>• After you've been taking Gilenya for 3–4 months</li></ul>

\* Your neurologist or MS nurse will tell you more about the testing you'll need during treatment. Please ensure that you have all of the necessary tests at the recommended times.

\*\* Not required if you have had chickenpox or were previously vaccinated



## Pregnancy

It's generally advisable to avoid taking medications during pregnancy because they may cause harm to the developing fetus. The best approach is to talk to your doctor or MS nurse before becoming pregnant so you can work out a schedule for stopping and re-starting your medication.



Gilenya should not be taken during pregnancy or breastfeeding



Women should use a reliable method of contraception during treatment.

Call your MS nurse if you are planning a pregnancy. Gilenya takes about 2 months to be eliminated from your body after you stop taking it, so it's best to wait until the drug is gone before trying to get pregnant. Gilenya should not be taken while you are breastfeeding. Contact your neurologist or MS nurse if you become pregnant while taking Gilenya.

Once your baby is born and weaned, your MS nurse can schedule an appointment at a first-dose clinic so you can re-start Gilenya.



**Always use a reliable method of contraception while taking an MS medication. Talk to your doctor or MS nurse if you are planning a pregnancy in the next few months.**



## Other medications

All medications have the potential to interact with other drugs you are taking. This includes other prescription medications, as well as non-prescription drugs and alternative/complementary therapies. Some of these medications can also worsen MS symptoms.

Talk to a healthcare professional before taking any new medication. Your doctor, MS nurse or pharmacist can advise you about interactions that may occur with Gilenya and the other medications you are taking.

## Other medical conditions

Always ensure that your doctor is aware of any other medical conditions you may have. This includes high blood pressure, liver problems, diabetes, infections, or other illnesses.

## Resources in your community

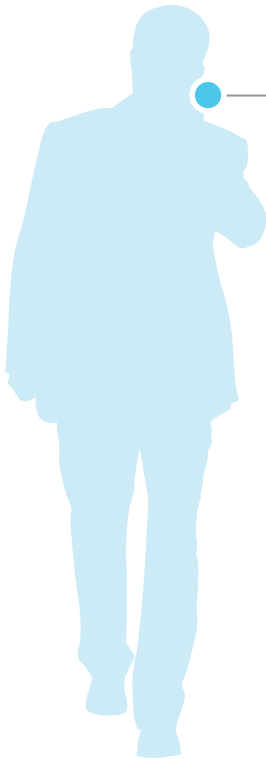
Your neurologist or MS nurse will talk to you about the Gilenya Go Program™, which provides information and support for people taking Gilenya.

Your local pharmacist can also provide important advice on your medication, how to take it, and what other medications (including non-prescription and alternative/complementary therapies) to avoid.



## Contacting your MS nurse

Contact your MS nurse if you have any questions or concerns about your medication. It is important to notify your doctor or MS nurse if you have any new, worrisome or unusual symptoms that may be related to your medication, or any worsening of your MS symptoms.



Notify your doctor or MS nurse if you have any new symptoms










The MS Essentials series provides the latest information on multiple sclerosis medications, research, and lifestyle issues such as health, nutrition and exercise. All of the booklets are developed by Lind Publishing, publishers of MSology, to help people affected by MS remain active and informed. MS Essentials is provided free of charge. The full series of publications is available for download on <http://www.MSology.com>.

The information reflects use of the medication in Canada; use may vary in other countries. MSology does not approve, endorse or recommend any specific product or therapy. Contact your healthcare providers before you start treatment, alter the dose, interrupt or discontinue your therapy. For full information about a specific medication, consult the prescribing information or package insert provided by the manufacturer for your country.





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