

Patient / Parent and Caregiver Medication Guide

Important things to know about
Gilenya® (fingolimod) treatment.

To be distributed by Healthcare Professionals to patients prescribed with Gilenya® (Fingolimod)



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Introduction

Your doctor has prescribed Gilenya® (Fingolimod) for you or your child. Gilenya® (Fingolimod) is a once-daily oral therapy for the treatment of relapsing-remitting multiple sclerosis (RRMS). Gilenya® (Fingolimod) does not cure MS, but it can

- Reduce the number of relapses (also called attacks or flare-ups)
- Slow down the progression of physical disabilities due to MS

This guide is designed to offer important information that you need to know if you or a person in your care is starting treatment with Gilenya® (Fingolimod). Please speak to your doctor if you have any further questions about your treatment or the information in this guide.

Gilenya® (Fingolimod) is a prescription medicine used to treat RRMS in adult patients and paediatric patients of 10 years of age and above.

What is multiple sclerosis?

Multiple sclerosis is a long-term condition that affects the central nervous system, which is made up of the brain and spinal cord. In multiple sclerosis, the immune system attacks the protective sheath (called myelin) around the nerves in the central nervous system and stops the nerves from working properly. It can slow down or completely stop signals from passing between nerve cells, which causes the symptoms of multiple sclerosis.

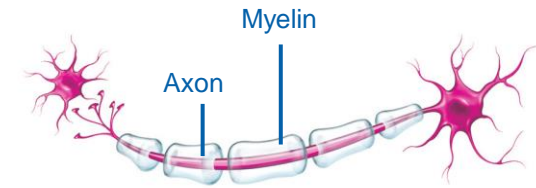
There are different forms of multiple sclerosis. The most common is relapsing-remitting multiple sclerosis. People with this type of multiple sclerosis will experience periods of relapse (or worsening), followed by periods of full or partial recovery. Relapsing-remitting multiple sclerosis is characterised by repeated attacks (relapses) that reflect inflammation within the central nervous system. Symptoms vary from patient to patient. Symptoms of a relapse may disappear completely when the relapse is over, but some problems may remain. Common symptoms that may be experienced during a relapse include

- Walking difficulties
- Numbness
- Vision problems
- Disturbed balance

How Multiple Sclerosis affects the Central Nervous System

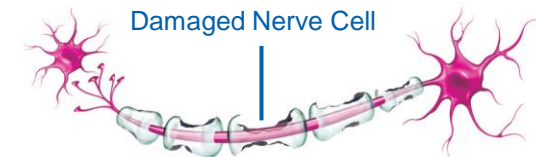
Normal nerve cell

In a healthy nerve cell, signals pass quickly down the axon, which lies beneath an insulating cover of myelin.



Damaged nerve cell

Attacks by the white blood cells (lymphocytes) of the immune system cause damage to this protective insulation.



Using Gilenya® (Fingolimod) to treat MS

What is Gilenya® (Fingolimod)?

Gilenya® (Fingolimod) is used in adults and paediatric patients (10 years of age and above) to treat relapsing-remitting multiple sclerosis (MS) by helping to reduce the number of relapses (flare-ups) and to slow down the progression of physical disabilities due to MS.

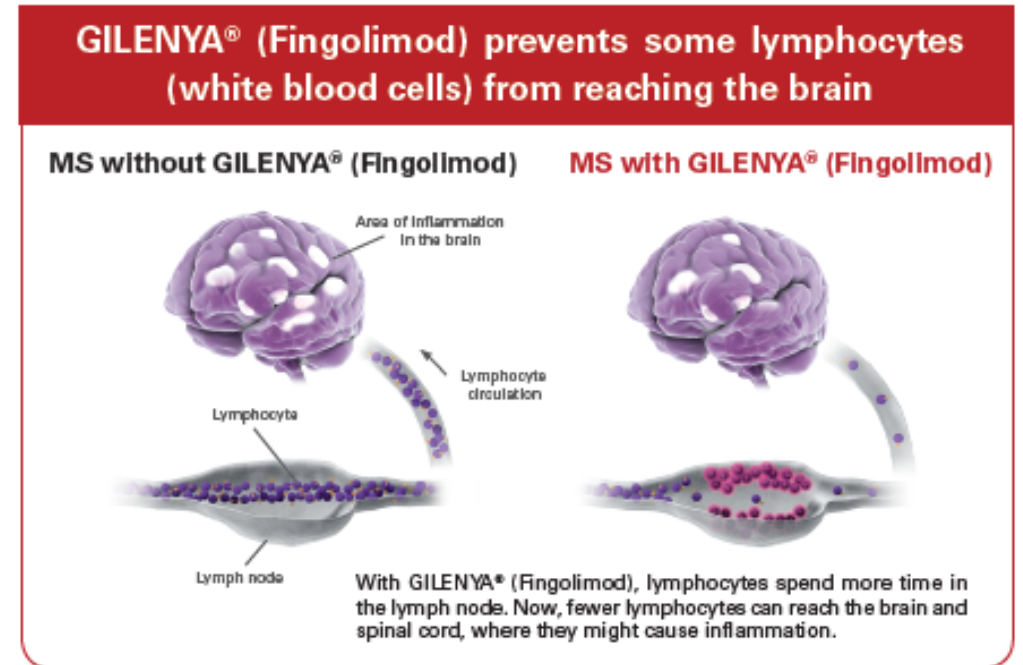
Gilenya® (Fingolimod) is provided as a once-daily capsule for both adult and paediatric patients.

The active ingredient in Gilenya® is called fingolimod (fin-GOL-eh-mod).

How does Gilenya® (Fingolimod) work?

Immune cells (lymphocytes) that interact with Gilenya® (Fingolimod) become trapped in the lymph nodes which stops them from reaching the brain and spinal cord, **preventing** them from causing inflammation.

This limits the nerve damage caused by MS. Gilenya® (Fingolimod) also reduces some of the immune reactions of your or your child's body.



What are the possible side effects of Gilenya® (Fingolimod)?



Like all medicines, Gilenya® (Fingolimod) may cause side effects, although not everybody experiences them.

If any of the side effects gets serious, or if you notice any side effects not listed in this Patient/Parent/Caregiver Medication Guide, please tell your doctor or pharmacist.

Very common – affects more than 1 patient in 10	Some common side effects could be or could become serious – affects 1 to 10 patients in 100	
<ul style="list-style-type: none">• Infection with flu virus (with symptoms such as tiredness, chills, sore throat, joint or muscle aches, fever)• Sinusitis• Headache• Diarrhoea• Back pain• Cough• Increase in blood levels of a liver enzyme (ALT, AST and GGT)	<ul style="list-style-type: none">• Slow heartbeat (bradycardia) and irregular heart rhythm at initiation• High blood pressure (Hypertension)• Increased blood triglycerides• Difficulty breathing or shortness of breath (Dyspnoea)• Blurring or changes in vision• Fungal infection of the skin resulting in small, discolored patches (Tinea versicolor)• Lower count of white blood cells which may increase your chance of an infection• Reduced level of a certain type of blood cell called a lymphocyte (Lymphopenia)• Eczema• Pruritus	<ul style="list-style-type: none">• Abnormal physical weakness or lack of energy (Asthenia)• Cough with phlegm, chest discomfort, and fever (signs of a lung disorder)• Feeling sick, with nausea, vomiting, and diarrhoea• Dizziness or migraine• Herpes virus infection (shingles, or herpes zoster) with symptoms such as blisters, burning, itching, or pain around the mouth or genitals. Other symptoms may be fever and weakness in the early stages of infection, followed by numbness, itching, and red patches or blisters on the face or trunk• A type of skin cancer call basal cell carcinoma has been reported in MS patients treated with Gilenya® (Fingolimod)

ALT = alanine transaminase, AST = aspartate transaminase, GGT = gamma-glutamyl transpeptidase

Precautions and contraindications



Please note:

- Contact your doctor immediately if you or your child experiences any adverse reactions during treatment with Gilenya® (Fingolimod) or in case of pregnancy
- Please tell any doctor you see that you or your child is taking Gilenya® (Fingolimod)



Cardiac diseases and medication:

- Inform your doctor if you or your child has **underlying cardiac conditions, including previous episode of heart attack, stroke, heart failure and irregular or abnormal heartbeat**
- Inform your doctor if you or your child is taking medicines that are known to **decrease heart rate**
- If the above 2 conditions apply to you or your child, Gilenya® (Fingolimod) may not be appropriate for you or your child. If your doctor considers that there is benefit for you or your child to be treated with Gilenya® (Fingolimod), he or she will want you or your child to be seen by a cardiologist (heart specialist) to advise on how to best start treatment:
 - Whether you or your child can be switched to another medication
 - How long you or your child should be monitored after taking the first dose of Gilenya® (Fingolimod), which could include an overnight stay

Precautions and contraindications



Infections:

- Your doctor will monitor blood lymphocyte (white blood cell) counts prior to starting treatment with Gilenya® (Fingolimod)



Liver function:

- Inform your doctor if you or your child has liver problems



Pregnancy:

- Gilenya® (Fingolimod) **should not be used** in women who are pregnant or women who could become pregnant, who are not using effective contraception.
- If you or your child is a woman who could become pregnant, you should be informed by your or your child's doctor about the serious risks to the fetus caused by Gilenya® (Fingolimod).
- If you or your child is a woman of child-bearing potential, you or your caregiver will be provided with a **Pregnancy-Specific Patient Reminder Card**.

Precautions and contraindications

If you are elderly: Experience with Gilenya® (Fingolimod) in elderly patients (older than 65 years of age) is limited. Talk to your doctor if you have any concerns.

If your child is under 10: Gilenya® (Fingolimod) is not intended to be used in children younger than 10 years of age, as it has not been studied in patients with MS younger than 10 years old.

If you or your child needs to drive and use machines: Your doctor will tell you whether your illness allows you to drive vehicles and use machines safely. Gilenya® (Fingolimod) is not expected to have an influence on your ability to drive and use machines.

If you or your child is a woman of childbearing age: Your doctor will ask you or your child to have pregnancy tests in order to ensure that you or your child is not pregnant. You or your child should avoid becoming pregnant while taking Gilenya® (Fingolimod) or for 2 months after stopping treatment because there is a risk of harm to the unborn baby. (Women taking Gilenya® (Fingolimod) should not breast-feed.) Women of child bearing age should use effective contraception while on Gilenya® (Fingolimod) treatment and in the 2 month after discontinuation. Your doctor will also provide you or your child with a Pregnancy-Specific Patient Reminder Card.

Before starting Gilenya® (Fingolimod) treatment



Screenings:

- **Before taking the first dose, you will have:**
 - A baseline electrocardiogram (ECG) to assess the action of your heart
 - A blood pressure measurement
 - Blood test to assess your liver function if it has not been done recently (within 6 months)
 - Blood tests to assess your white blood cell count and immunity against the virus that causes chickenpox
 - A review of medication you or your child is taking
- Your doctor may arrange an **eye assessment** before starting Gilenya® (Fingolimod) as well as a follow-up eye assessment 3-4 months after starting treatment.
- For women of child-bearing potential, your or your child's doctor will ask you or your child to take a **pregnancy test** to ensure that you or your child is **not** pregnant before you or your child starts treatment with Gilenya® (Fingolimod) .
- Your or your child's doctor will arrange magnetic resonance imaging **(MRI) scans** before you or your child starts treatment and during treatment to monitor the risk of **progressive multifocal leukoencephalopathy (PML), a rare brain disorder caused by an infection that may lead to severe disability or death.**

How is Gilenya® (Fingolimod) taken?

While taking Gilenya® (Fingolimod), your or your child's treatment will be overseen by a doctor who is experienced in the treatment of MS. Always take Gilenya® (Fingolimod) exactly as your or your child's doctor has told you. You should check with your or your child's doctor if you are not sure.

- In adults, the recommended dose of Gilenya® (Fingolimod) is one 0.5 mg capsule taken orally once daily.
- In paediatric patients (10 years of age and above), the recommended dose is dependent on body weight:
 - Paediatric patients with body weight \leq 40 kg: one 0.25 mg capsule daily taken orally.
 - Paediatric patients with body weight $>$ 40 kg: one 0.5 mg capsule daily taken orally.
- Take Gilenya® (Fingolimod) once a day with a glass of water. Gilenya® (Fingolimod) can be taken with or without food.
- Taking Gilenya® (Fingolimod) at the same time each day will help you remember to take it.
- If you have any questions about how long to take Gilenya® (Fingolimod), talk to your or your child's doctor or pharmacist.
- Do not stop taking Gilenya® (Fingolimod) or change your dose without talking to your or your child's doctor first.
- If you or your child forgets to take Gilenya® (Fingolimod), take the next dose as planned. Do not take a double dose to make up for a forgotten dose.

Do not exceed the recommended dose.

If you or your child takes more Gilenya® (Fingolimod) than you should, call your or your child's doctor straight away.

The first time you or your child takes Gilenya® (Fingolimod)



Slow heart rate or irregular heartbeat:

- At the beginning of treatment, Gilenya® (Fingolimod) causes the heart rate to slow down. This may make you feel dizzy or lower your blood pressure. Gilenya® (Fingolimod) can also cause an irregular heartbeat, especially after the first dose. **Immediately inform your doctor** if you or your child experiences symptoms such as dizziness, nausea, vertigo, or palpitations or if you or your child feels uncomfortable after taking the first dose of Gilenya® (Fingolimod).



6-hour monitoring:

After you or your child has taken the first dose, your doctor will ask you or your child to stay at the surgery or clinic for at least 6 hours so that appropriate measures can be taken if side effects occur. In some circumstances, overnight stay may be required. During the 6-hour monitoring, you or your child will have:

- Pulse and blood pressure checked every hour
 - You or your child may be monitored with a continuous ECG during this time
- An ECG and blood pressure checked at the end of 6 hours

If, after the 6-hour period, any of the following apply to you or your child, you or your child may need to be monitored for a longer period until these have resolved:

- Very slow heart rate
- Heart rate is still decreasing
- ECG shows certain abnormalities
- Slow heart rate with concomitant low blood pressure

While you or your child is taking Gilenya® (Fingolimod)



Treatment Interruption:

Call your or your child's doctor in case of treatment interruption:

If you or your child has stopped Gilenya® (Fingolimod) for 1 day or more during the first 2 weeks of treatment, or for more than 7 days during weeks 3 and 4 of treatment, or if you or your child has stopped Gilenya® (Fingolimod) for more than 2 weeks after having been on treatment for at least 1 month, the initial effect on your or your child's heart rate may occur again. When you or your child restarts Gilenya® (Fingolimod) therapy, your or child's doctor may decide to monitor you or your child with heart rate and blood pressure measurements every hour, to run ECGs, and if needed, to monitor you or your child overnight. Do not restart Gilenya® (Fingolimod) after stopping it without seeking advice from your or your child's doctor.



Visual symptoms:

- Gilenya® (Fingolimod) may cause swelling at the back of the eye, a condition that is known as macular edema. Tell your or your child's doctor if you or your child experiences any changes in your vision during and up to 2 months after stopping treatment.
- If you or your child has diabetes or have had inflammation of the eye (uveitis), your or your child's doctor will want you or your child to undergo additional regular eye examinations, as your or your child's chances of developing macular edema are known to be higher.
- Your or your child's doctor may arrange an eye assessment as required during treatment. A follow-up eye assessment may be done 3-4 months after starting treatment.

While you or your child is taking Gilenya® (Fingolimod)



Infections:

Because Gilenya® (Fingolimod) affects the immune system, people taking Gilenya® (Fingolimod) are more likely to get infections, including opportunistic infections that can be fatal, and may also increase the risk of developing certain malignancies. If you think you or your child has any of the following, during and up to two months after stopping treatment, **call your or your child's doctor straight away**: a headache accompanied by a stiff neck, sensitivity to light, fever, flu-like symptoms, nausea, rash, shingles and/ or confusion or seizures (fits) (possible symptoms of meningitis and/or encephalitis).

Blood lymphocyte (white blood cell) counts

Your or your child's doctor will measure blood lymphocyte counts during treatment with Gilenya® (Fingolimod) to monitor your ability to fight infection. Treatment with Gilenya® (Fingolimod) may be interrupted if blood lymphocyte count is too low.

While you or your child is taking Gilenya® (Fingolimod)



Worsening of MS symptoms:

Inform your or your child's doctor straight away if you believe your or your child's MS is getting worse or if you notice any new symptoms, during and after treatment with Gilenya® (Fingolimod) , for example:

- changes in mood or behaviour,
- new or worsening weakness on one side of the body,
- changes in vision,
- confusion,
- memory lapses,
- speech and communication difficulties.

These may be the symptoms of **progressive multifocal leukoencephalopathy**. Your doctor will arrange MRI scans during treatment to monitor the risk of PML.

Speak with your partner or caregivers and inform them about your treatment. Symptoms might arise that you might not become aware of by yourself.

While you or your child is taking Gilenya® (Fingolimod)



Skin cancer:

Skin cancers have been reported in multiple sclerosis patients treated with Gilenya® (Fingolimod). **Inform your or your child's doctor immediately** if you notice any skin nodules (e.g. shiny, pearly nodules), patches or open sores that do not heal within weeks. Symptoms of skin cancer may include abnormal growth or changes of skin tissue (e.g. unusual moles) with a change in color, shape or size over time.



Liver function:

Some cases of acute liver failure requiring liver transplant and clinically significant liver injury have been reported. Gilenya® (Fingolimod) can cause abnormal results in liver function tests. After starting Gilenya® (Fingolimod), you or your child will need a blood test at months 1, 3, 6, 9, and 12 and regularly thereafter until 2 months after Gilenya® (Fingolimod) discontinuation.

Inform your or your child's doctor if you notice:

- yellowing of your or your child's skin or the whites of your or your child's eyes,
- abnormally dark urine,
- pain on the right side of the stomach area,
- tiredness,
- feeling less hungry than usual,
- unexplained nausea and vomiting.

These can be signs of liver injury.

While you or your child is taking Gilenya® (Fingolimod)



Pregnancy:

- **Gilenya® (Fingolimod) should not be used in women who could become pregnant and are not using effective contraception, or who are pregnant.**
- Women of child-bearing potential should:
 - have their pregnancy status verified by their doctor at suitable intervals during Gilenya® (Fingolimod) treatment,
 - receive regular counseling from a healthcare professional facilitated by the Pregnancy-Specific Patient Reminder Card about the serious risks of Gilenya® (Fingolimod) to the fetus,
 - use effective contraception whilst taking Gilenya® (Fingolimod), and in the 2 months after you or your child stops taking the treatment because of the serious risks to the fetus caused by Gilenya® (Fingolimod),
 - immediately report to your or your child's doctor any (intended or unintended) pregnancy during treatment and for 2 months following discontinuation of treatment with Gilenya® (Fingolimod).



Blood Pressure

Gilenya® (Fingolimod) causes a slight elevation of blood pressure, so your or your child's doctor may want to check your or your child's blood pressure regularly. It is important that your or your child's blood pressure is properly controlled.

Stopping Gilenya® (Fingolimod) therapy may result in return of disease activity. Your or your child's doctor will decide whether and how you or your child needs to be monitored after stopping Gilenya® (Fingolimod).

Paediatric patients

Please note: All adult precautions and contraindications apply also for paediatric patients.

In addition:



Screenings:

- **For paediatric patients, in addition to the screenings listed on slide 9, their doctor will also assess:**
 - Height and weight
 - Puberty status
 - Vaccination status



6-hour monitoring:

- For paediatric patients, 6-hour monitoring (or similar precautions) will also be taken when the dose is increased from 0.25 mg to 0.5 mg once daily.



HSA Approved RMP - Patient/Parent/Caregiver Medication Guide

This material is also available online.

Please scan this QR code

or visit <https://www.medhub.novartis.com.sg/ermp/Gilenya>

If you have any questions about the information in this guide, please contact your doctor.

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