
Understanding your or your child's treatment with GILENYA® (Fingolimod)

**A guide for people with relapsing-
remitting MS**

MS=multiple sclerosis

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

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



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

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What is MS?



MS is a long-term condition that affects the central nervous system (CNS). The CNS is made up of the brain and spinal cord. In MS, inflammation destroys the protective sheath (called myelin) around the nerves in the CNS 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 MS.

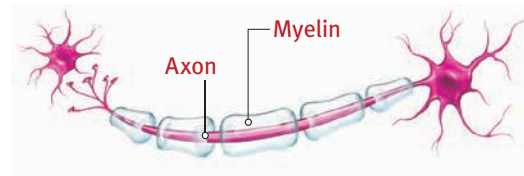
There are different forms of MS. The most common is Relapsing-remitting MS (RRMS). People with this type of MS will experience periods of relapse (or worsening), followed by periods of full or partial recovery. RRMS is characterised by repeated attacks (relapses) that reflect inflammation within the CNS. 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 MS affects the CNS

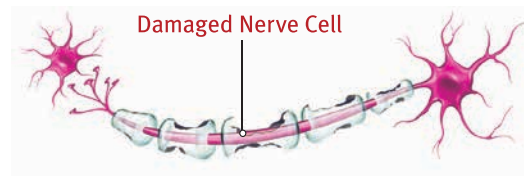
Normal nerve cell

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.



RRMS = relapsing-remitting CNS = central nervous system

Using GILENYA® (Fingolimod) to treat MS



What is GILENYA® (Fingolimod)?

GILENYA® (Fingolimod) is used in adults and pediatric 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 pediatric patients.

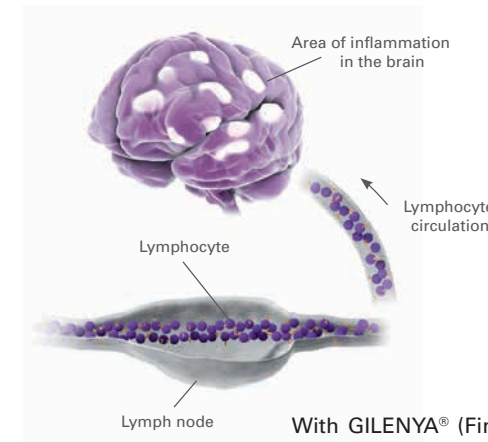
The active ingredient in GILENYA® is called fingolimod (fin-GOL-eh-mod).

How does GILENYA® (Fingolimod) work?

GILENYA® (Fingolimod) helps to protect against attacks on the CNS by the immune system by reducing the ability of some white blood cells (lymphocytes) to move freely within the body and by stopping them from reaching the brain and spinal cord. This limits nerve damage caused by MS. GILENYA® (Fingolimod) also reduces some of the immune reactions of your or your child's body.

GILENYA® (Fingolimod) prevents some lymphocytes (white blood cells) from reaching the brain

MS without GILENYA® (Fingolimod)



MS with GILENYA® (Fingolimod)



With GILENYA® (Fingolimod), lymphocytes spend more time in the lymph node. Now, fewer lymphocytes can reach the brain and spinal cord, where they might cause inflammation.

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 Guide, please tell your doctor or pharmacist.

Very common – affects more than 1 patient in 10

- | | |
|---|---|
| • Infection with flu virus (with symptoms such as tiredness, chills, sore throat, joint or muscle aches, fever) | • Diarrhoea |
| • Sinusitis | • Back pain |
| • Headache | • Cough |
| | • Increase in blood levels of a liver enzyme (ALT, AST and GGT) |

Some common side effects could be or could become serious – affects 1 to 10 users in 100

- 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 have been reported in MS patients treated with GILENYA® (Fingolimod)

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

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

Some common side effects could be or could become serious – affects 1 to 10 users in 100

- 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
- Abnormal physical weakness or lack of energy (Asthenia)

Do not take GILENYA® (Fingolimod) if you or your child



- Have a lowered immune response due to an immunodeficiency syndrome or because of medicines that suppress the immune system
- Have a severe active infection or active chronic infection, such as hepatitis or tuberculosis
- Have an active cancer
- Have severe liver problems
- Are allergic to fingolimod or any of the other ingredients of GILENYA® (Fingolimod)
- have had heart attack, angina, stroke or warning of a stroke or certain types of heart failure in the last 6 months
- have certain types of irregular or abnormal heartbeat (arrhythmia), including patients in whom the electrocardiogram (ECG) shows prolong QT interval before starting fingolimod
- are taking or have recently taken medicines for irregular heartbeat such as quinidine, disopyramide, amiodarone or sotalol



If any of these conditions apply to you or your child, tell your doctor before taking GILENYA® (Fingolimod).

Take special care with GILENYA® (Fingolimod)



If any of the following apply to you or your child, talk to your doctor before taking GILENYA® (Fingolimod), as it may not be appropriate for you or your child.

If you or your child have specific cardiac diseases or are taking medication that decreases your or your child's heart rate: GILENYA® (Fingolimod) may not be appropriate for you or your child, please tell your doctor about such condition before being treated with Fingolimod. 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

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 need 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 are 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 are 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® treatment



Human papilloma virus (HPV)-related cancer – Your doctor will assess whether you need to undergo cancer screening (including a Pap test) and if you should receive the HPV vaccine.



Liver function – Gilenya can cause abnormal results in liver function tests. You will need a blood test prior to treatment initiation with Gilenya.



Seizures – Seizures may occur during treatment. Inform your doctor if you or a family member have a history of epilepsy.

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 ≤ 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 forget 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's take more GILENYA® (Fingolimod) than you should, call your or your child's doctor straight away.

The first time you or your child take GILENYA® (Fingolimod)



Slow heart rate and 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. If you experience symptoms such as dizziness, nausea, vertigo, or palpitations or feel uncomfortable after taking the first dose of GILENYA® (Fingolimod), please immediately inform your doctor.

Before you take the first dose, you will have:

- A baseline electrocardiogram (ECG) to assess the action of your heart
- A blood pressure measurement
- A review of medication you are taking
- Blood tests to assess your white blood cell count, immunity against the virus that causes chickenpox and liver function
- A pregnancy test to ensure that you are not pregnant because of the serious risks of GILENYA® (Fingolimod) to the foetus
- A cardiovascular assessment, especially if you have a history of heart problems
- An eye examination, especially if you have or have had eye conditions or diabetes

Pediatric patients will also be weighed and measured, and will undergo a physical development assessment and an immunization status check.

After you have taken the first dose, your doctor will ask you to stay at the surgery or clinic for at least 6 hours. During the 6-hour monitoring, you will have:

- Your pulse and blood pressure checked every hour
 - You may be monitored with a continuous ECG during this time
- ECG and blood pressure checked at the end of 6 hours

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

- You have a very slow heart rate
- Your heart rate is still decreasing
- Your ECG shows certain abnormalities
- You have a slow heart rate with concomitant low blood pressure

Similar precautions will also be taken when your child's dose is increased from 0.25mg to 0.5mg once daily.

While you are taking GILENYA® (Fingolimod)



Infections – Because GILENYA® (Fingolimod) affects the immune system, you or your child 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 have 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 and/or confusion or seizures (fits) (possible symptoms of meningitis and/or encephalitis, either caused by fungal or viral infections).

If you believe your or your child's MS is getting worse (e.g. weakness or visual changes) or if you notice any new symptoms, talk to your or your child's doctor as soon as possible. These may be the symptoms of a rare brain disorder called progressive multifocal leukoencephalopathy (PML), which is caused by an infection.



Skin cancer – Skin cancers have been reported in MS 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.



Blood tests – GILENYA® (Fingolimod) can cause abnormal results in liver function tests and white blood cell counts. You or your child will need a blood test prior to treatment initiation and at months 1, 3, 6, 9, and 12 during GILENYA® (Fingolimod) therapy and regularly thereafter.

Some cases of acute liver failure requiring liver transplant and clinically significant liver injury have been reported. Inform your or your child's doctor if they notice yellowing of 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 or unexplained nausea and vomiting as these can be signs of liver injury.

White blood cell counts will be measured at regular intervals as decided by your doctor to monitor your ability to fight infection.

While you are taking GILENYA® (Fingolimod)



Pregnancy – You or your child should avoid becoming pregnant and should use effective contraception whilst taking GILENYA® (Fingolimod), and in the two months after stopping the treatment because there is a risk of harm to the unborn baby. Talk with your or your child's doctor about reliable methods of birth control that you or your child should use.

Immediately report to your or your child's doctor any (intended or unintended) pregnancy during and for two months following discontinuation of treatment with GILENYA® (Fingolimod). Women of child-bearing potential (including female adolescents) should have pregnancy tests repeated at suitable intervals during GILENYA® (Fingolimod) treatment.



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 about any changes in vision during and up to two months after stopping treatment. If you or your child have diabetes or have had inflammation of the eye (uveitis), your doctor will want you to undergo additional regular eye examinations, as your chances of developing macular oedema are known to be higher.



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 doctor will decide whether and how you need to be monitored after stopping GILENYA® (Fingolimod).

While you are taking GILENYA® (Fingolimod)



Call your or your child's doctor in case of treatment interruption. If you or your child have stopped GILENYA® (Fingolimod) for at least 1 day or more during the first 2 weeks of treatment, or more than 7 days during weeks 3 and 4 of treatment, or if you or your child have stopped GILENYA® (Fingolimod) for more than 2 weeks after being on treatment for more than a month, the initial effect on your or your child's heart rate may occur again. When you or your child restart GILENYA® (Fingolimod) therapy, your or your 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 overnight. Do not restart GILENYA® (Fingolimod) after stopping it without seeking advice from your or your child's doctor.

Gilenya® is a registered trademark of Novartis Pharma AG



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