Patient Guide: Important things to remember about your Gilenya® (fingolimod)▼ treatment

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

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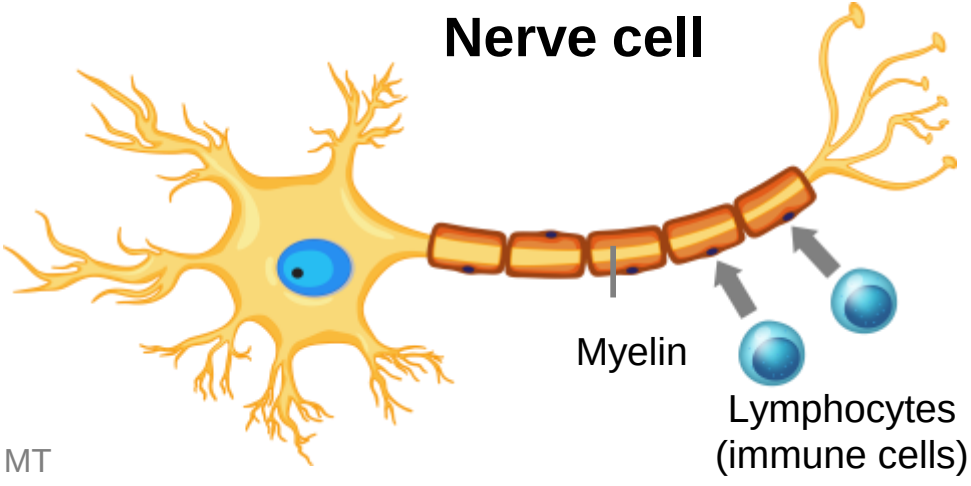
GIL PC1 02/21 MT

What is multiple sclerosis?

MS is a long-term condition that affects the central nervous system (CNS), comprised 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. This is called demyelination.

Relapsing-remitting MS is characterised by repeated attacks (relapses) that reflect inflammation within the CNS. Symptoms vary from patient to patient.

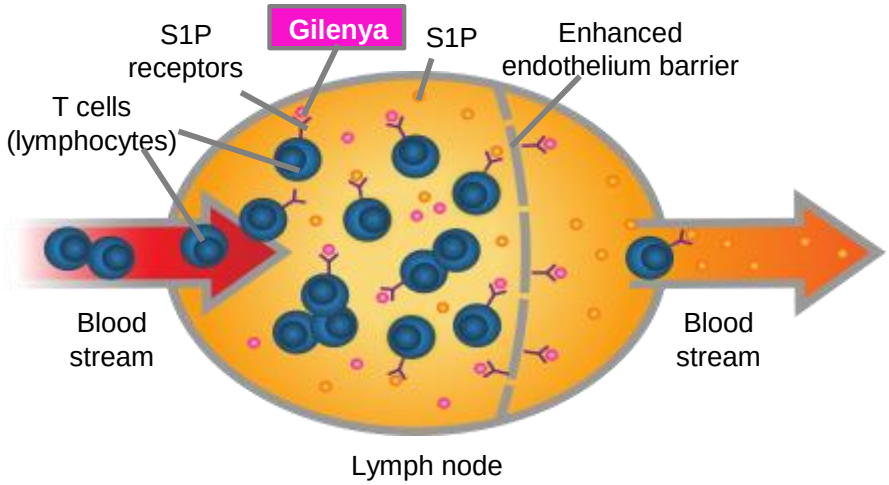
Symptoms of a relapse may disappear completely when the relapse is over, but some problems may remain



How does Gilenya work?

It is not fully understood how Gilenya therapy works in MS.

Gilenya 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 also reduces some of the immune reactions of your body.



Contraindications and precautions

Gilenya (fingolimod) should not be used in patients with specific-cardiac diseases, and is not recommended in patients who are also taking medicines that are known to decrease heart rate.

Gilenya should not be used in women who are pregnant and women of child-bearing potential (including female adolescents) not using effective contraception.

Your doctor will ask you to stay at the surgery or clinic for six or more hours after taking the first dose so that appropriate measures can be taken if side effects occur. In some circumstances, an overnight stay may be required.

For pediatric patients, similar precautions will also be taken when the dose is increased from 0.25 mg to 0.5 mg once daily.

Contraindications and precautions

All women of child-bearing potential (including female adolescents) will be provided with a Pregnancy-Specific Patient Reminder Card.

Please read the Patient Information Leaflet thoroughly before starting treatment with Gilenya.

Please inform your doctor if you or a family member have a history of epilepsy.

Contact your doctor immediately if you experience any adverse reactions during treatment with Gilenya or in case of pregnancy.

Please tell any doctor you see that you are taking Gilenya.

Before starting Gilenya treatment

Pregnancy – Gilenya is teratogenic. Women of child-bearing potential (including female adolescents) should be informed by their doctor about Gilenya's serious risks to the fetus, they must have a negative pregnancy test (verified by a healthcare professional), and must take effective contraception before starting treatment with Gilenya.

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.

The first time you take Gilenya

Slow heart rate and irregular heartbeat

At the beginning of treatment, Gilenya causes the heart rate to slow down. This may make you feel dizzy or lower your blood pressure. If you experience symptoms such as dizziness, nausea, vertigo, or palpitations or feel uncomfortable after taking the first dose of Gilenya, 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

Pediatric patients will also be weighed and measured, and will undergo a physical development assessment.

The first time you take Gilenya

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
- An ECG at the end of 6 hours

Call your doctor in case of treatment interruption. If you have stopped Gilenya 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 have stopped Gilenya for more than 2 weeks after you have been on treatment for at least 1 month, the initial effect on your heart rate may occur again. When you restart your Gilenya therapy, your doctor may decide to monitor you with heart rate and blood pressure measurements every hour, to run ECGs, and if needed, to monitor you overnight.

While you are taking Gilenya

Infections – Because Gilenya affects the immune system, you are more likely to get infections. If you think you have any of the following, during and up to 2 months after stopping treatment, call your 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, either caused by fungal or viral infection).

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

While you are taking Gilenya

Skin cancer – Skin cancers have been reported in multiple sclerosis patients treated with Gilenya. Inform your 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. You will need a blood test at months 1, 3, 6, 9, and 12 during Gilenya therapy and regularly thereafter, until 2 months after Gilenya discontinuation. Patients should inform their doctor if they notice yellowing of their skin or the whites of their 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.

While you are taking Gilenya

Pregnancy – Women of child-bearing potential (including female adolescents) must have pregnancy tests repeated at suitable intervals during Gilenya treatment.

You should receive regular counseling from a healthcare professional facilitated by the Pregnancy-Specific Patient Reminder Card about the serious risks of Gilenya to the fetus.

You must use effective contraception whilst taking Gilenya, and in the 2 months after you stop taking the treatment because of Gilenya's serious risks to the fetus.

Immediately report to your doctor any (intended or unintended) pregnancy during and for 2 months following discontinuation of treatment with Gilenya.

While you are taking Gilenya

Visual symptoms – Gilenya may cause swelling at the back of the eye, a condition that is known as macular edema. Tell your doctor about any changes in your vision during and up to 2 months after stopping treatment.

Depression and anxiety – Both conditions have been reported in pediatric patients treated with Gilenya. Talk to your doctor if you are experiencing symptoms.

Stopping Gilenya therapy may result in return of disease activity. Your doctor will decide whether and how you need to be monitored after stopping Gilenya.

Suspected Adverse Drug Reactions (side effects) and medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at http://www.medicinesauthority.gov.mt/adrportal and sent by post or email to;

P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann. SGN 3000.

E: postlicensing.medicinesauthority@gov.mt.

Healthcare Professionals may also report any adverse events associated with the use of **Gilenya** to Novartis Pharma Services Inc., Representative Office, Malta, by phone on +356 21222872, online on www.report.novartis.com or by e-mail at drug_safety.malta@novartis.com.

Marketing Authorization Holder: Novartis Europharm Limited, Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland.

Local Representative: Novartis Pharma Services Inc., Representative Office Malta.

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