Parents and Caregivers Guide: Important things to remember about Gilenya® (fingolimod) ▼ treatment

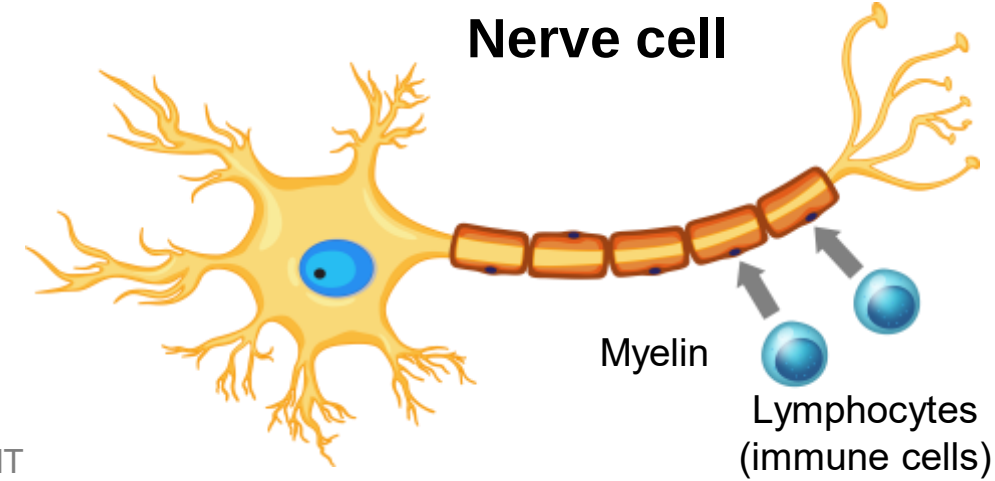
▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

What is multiple sclerosis?

Multiple sclerosis (MS) is considered an immune-mediated disease – perhaps autoimmune.

The immune system attacks the myelin coating that surrounds nerve cells in the central nervous system (CNS), which is made up of the brain and spinal cord

Its name comes from the scarring caused by inflammatory attacks at multiple sites in the CNS.

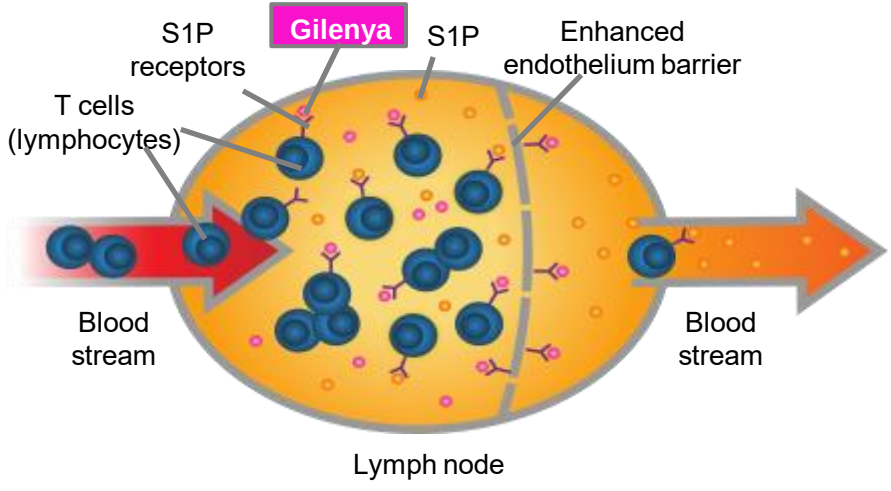


How does Gilenya work?

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

Gilenya binds to white blood cells (lymphocytes) in the blood by interacting with proteins on the cell surface known as sphingosine 1-phosphate (S1P) receptors.

White blood cells that interact with Gilenya become trapped in the lymph nodes, which prevents them from crossing into the CNS and causing inflammation and damage.



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

The doctor will ask the child/adolescent in your care 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.

Similar precautions will be taken if their dose is increased from 0.25 mg to 0.5 mg once daily.

Contraindications and precautions

If you are the parent/carer of a female adolescent of child-bearing potential, you will be provided with a Pregnancy-Specific Patient Reminder Card.

Please read the Patient Information Leaflet thoroughly before the child/adolescent in your care starts treatment with Gilenya.

Please inform the doctor if the child/adolescent in your care, or someone related to them, has a history of epilepsy.

Contact your doctor immediately if the child/adolescent in your care experiences any adverse reactions during treatment with Gilenya.

Any doctors that the child/adolescent sees should be told they are taking Gilenya.

Before starting Gilenya treatment

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

Human papilloma virus (HPV)-related cancer – The doctor will assess whether the child/adolescent in your care needs to undergo cancer screening (including a Pap test), and if they should receive the HPV vaccine.

Before starting Gilenya treatment

Liver function – Gilenya can cause abnormal results in liver function tests. The child/adolescent in your care will need a blood test prior to treatment initiation with Gilenya therapy.

Seizures – Seizures may occur during treatment. Inform the doctor if the child/adolescent in your care, or someone related to them, has 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 cause dizziness or lower the blood pressure. If the child/adolescent in your care experiences symptoms such as dizziness, nausea, vertigo, or palpitations or feels uncomfortable after taking the first dose of Gilenya, please immediately inform their doctor.

Before taking the first dose, the child/adolescent **will have:**

- A baseline electrocardiogram (ECG) to assess the action of their heart
- A blood pressure measurement
- A physical development assessment
- Height and weight measurements taken

The first time you take Gilenya

During the 6-hour monitoring:

- Pulse and blood pressure will be checked every hour
  - The child/adolescent may be monitored with a continuous ECG during this time
- An ECG at the end of 6 hours

Call their doctor in case of treatment interruption. If the child/adolescent has 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 Gilenya has been stopped for more than 2 weeks after being on treatment for at least month, the initial effect on the heart rate may occur again. When Gilenya therapy is restarted, the doctor may decide to monitor heart rate and blood pressure measurements every hour, to run ECGs, and if needed, to monitor the child/adolescent overnight.

While you are taking Gilenya

Infections – Because Gilenya affects the immune system, the child/adolescent is more likely to get infections. If you think they have any of the following, during and up to 2 months after stopping treatment, call their doctor straight away:
an infection, the flu, a headache accompanied by a stiff neck, sensitivity to light, nausea and/or confusion (possible symptoms of meningitis).

If you believe their MS is getting worse (e.g. weakness or visual changes) or if you notice any new symptoms, talk to their 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 their doctor immediately if you notice the child/adolescent has 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 – Gilenya can cause abnormal results in liver function tests. The child/adolescent in your care will need a blood test at months 1, 3, 6, 9, and 12 during Gilenya therapy and regularly thereafter.

While you are taking Gilenya

Pregnancy – Female adolescents of child-bearing potential **must** have pregnancy tests repeated at suitable intervals during Gilenya treatment.

The female adolescent in your care **must** receive regular counselling facilitated by the Pregnancy-Specific Patient Reminder Card from a healthcare professional about the serious risks of Gilenya to the fetus

The female adolescent in your care **must** use effective contraception whilst taking Gilenya, and in the 2 months after stopping taking the treatment because of Gilenya's serious risks to the fetus.

Immediately report to their 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 the doctor if the child/adolescent in your care experiences any changes in their vision during and up to 2 months after stopping treatment.

Depression and anxiety – Both conditions have been reported in children/adolescents treated with Gilenya. If the child/adolescent in your care is experiencing symptoms talk to their doctor.

Stopping Gilenya therapy may result in return of disease activity. The doctor will decide whether and how the child/adolescent needs to be monitored after stopping Gilenya.

For more information please refer to the package leaflet.

Suspected adverse reactions and medication errors associated with the use of Gilenya should be reported to:

Malta Medicines Authority
Sir Temi Zammit Buildings,
Malta Life Sciences Park,
San Gwann. SGN 3000.

Or at: www.medicinesauthority.gov.mt/adrportal.

Alternatively at: Novartis Pharma Services Inc., Representative Office, Malta by phone on +356 21222872.

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

Local Representative: Novartis Pharma Services Inc., Representative Office Malta. Tel No.: +356 21222872.