Patient / Parent and Caregiver Guide

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

NOVARTIS | Reimagining Medicine

GILENYA/PC/RMP Vs.20.2/FEB 2025/FA-11417854 02 JUNE 2025

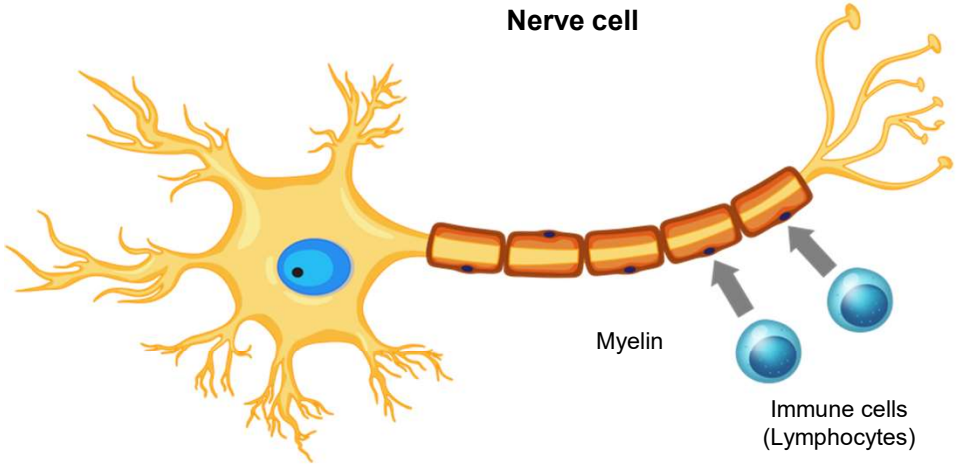
Welcome

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

Please note: The language throughout this guide directly addresses the patient. However, it is very important information for any parent or caregiver of a child or adolescent prescribed with Gilenya.

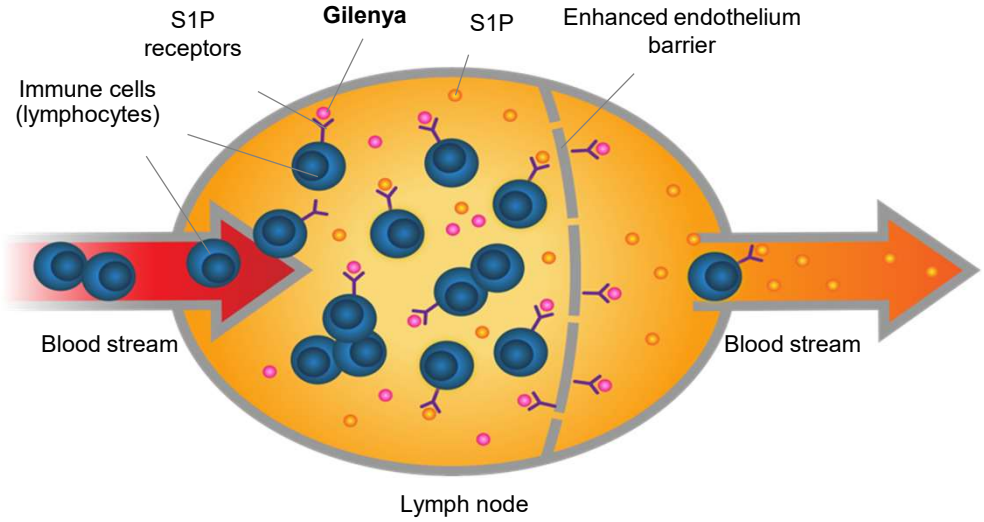
What is multiple sclerosis?

- Multiple sclerosis (MS) is a long-term condition that affects the central nervous system (CNS), which is made up of the brain and spinal cord.
- In MS, the immune system attacks the protective sheath (called myelin) around the nerves in the CNS. This stops the nerves from working properly.
- Relapsing-remitting MS (RMS) is characterized 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.
- Immune cells (lymphocytes) that interact with Gilenya become trapped in the lymph nodes which stops them from reaching the brain and spinal cord, **preventing** them causing inflammation.
- This limits the nerve damage caused by MS.
- Gilenya also reduces some of the immune reactions of your body.



Precautions and Contraindications

Please note:

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

Precautions and Contraindications

Cardiac diseases and medication:

- Inform your doctor if you have **underlying cardiac conditions**.
- Inform your doctor if you are taking medicines that are known to **decrease heart rate**.

Opportunistic infections risk:

- Your doctor will monitor blood lymphocyte counts prior to starting treatment with Gilenya.

Liver function:

- Inform your doctor if you have liver problems.

Precautions and Contraindications

Pregnancy:

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

Before starting Gilenya 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
  - Liver function tests will be taken prior to treatment initiation as Gilenya can cause abnormal results in liver function tests and liver injury
  - Blood lymphocyte counts will be performed prior to starting treatment with Gilenya

- Your doctor may arrange an **eye assessment** before starting Gilenya as well as a follow-up eye assessment 3-4 months after starting treatment.
- For women of child-bearing potential, a **pregnancy test** must be carried out and **negative results** verified by your doctor before starting treatment.
- Your doctor will arrange magnetic resonance imaging **(MRI) scans** before you start treatment and during treatment to monitor the risk of **progressive multifocal leukoencephalopathy (PML)**.

Taking Gilenya for the first time

Slow heart rate or irregular heartbeat:

- At the beginning of treatment, Gilenya causes the heart rate to slow down. This may cause dizziness or lower your blood pressure**. Immediately inform your doctor** if you experience any symptoms such as dizziness, nausea, vertigo, or palpitations which may be signs of a low heart rate, or if you feel uncomfortable after taking your first dose of Gilenya.

6-hour monitoring:

- 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.

During the 6-hour monitoring, you will have:

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

While taking Gilenya

Treatment Interruption:

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.

Visual symptoms:

- Gilenya may cause swelling at the back of the eye, a condition that is known as macular edema. Tell your doctor if you experience any changes in your vision during and up to 2 months after stopping treatment.
- Your doctor may arrange an eye assessment before starting Gilenya and as required during treatment. A follow-up eye assessment may be done 3-4 months after starting treatment.

While taking Gilenya

Infections:

Because Gilenya affects the immune system, people taking Gilenya 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).

Blood lymphocyte counts

Your doctor will monitor blood lymphocyte counts during treatment with Gilenya. Treatment with Gilenya may be interrupted if blood lymphocyte count is too low.

While taking Gilenya

Worsening of MS symptoms:

Inform your doctor straight away if you believe your MS is getting worse or if you notice any new symptoms, during and after treatment with Gilenya, 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** (PML is a rare brain disorder caused by an infection that may lead to severe disability or death) or of an inflammatory reaction (known as **immune reconstitution inflammatory syndrome** or IRIS) that can occur in patients with PML as Gilenya is removed from their body after they stop taking it. 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 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. After starting Gilenya, you will need a blood test at months 1, 3, 6, 9, and 12, and regularly thereafter while on treatment until 2 months after Gilenya discontinuation. **Inform your doctor immediately if you notice:**

- yellowing of your skin or the whites of your 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 taking Gilenya

Pregnancy:

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

Pediatric patients

Please note: All adult precautions and contraindications apply also for pediatric patients. **In addition:**

Screenings:

- **For pediatric patients, in addition to the screenings listed on slide 8, their doctor will also assess:**
  - Height and weight
  - Puberty status
  - Vaccination status

6-hour monitoring:

- For pediatric 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.

Depression and anxiety during treatment:

- Both depression and anxiety have been reported in pediatric patients treated with Gilenya. If the child/adolescent in your care is experiencing symptoms, talk to their doctor.

Further information and questions

- For more information about MS and Gilenya, please see http://www.medicinesauthority.gov.mt/rmm
- Please read the package insert for more detailed information about the appropriate use of Gilenya. For more detailed guidance on GILENYA please refer to the Summary of Product Characteristics (SmPC) available at https://www.ema.europa.eu/en/medicines/human/EPAR/gilenya
- Please speak to your doctor if you have any questions about the information in this guide.

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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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