

Important things to remember about your GILENYA (fingolimod) treatment





Your doctor will ask you to stay at the surgery or clinic for 6 or more hours after taking the first dose so that appropriate measures can be taken if side effects occur.



GILENYA[®] (fingolimod) is not recommended in patients with specific cardiac diseases or those taking medicines at the same time that are known to decrease heart rate. Please tell your doctor about such conditions before being treated with GILENYA. If the doctor considers that there is benefit for you to be treated with GILENYA, additional care and monitoring, including overnight stay, may be required.

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, vertigo, nausea, 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

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

If you have stopped GILENYA® (fingolimod) for at least 1 day during your first month of treatment, or if you have stopped GILENYA for more than 2 weeks after you have been on treatment for more than a 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—While you are taking GILENYA, you may get infections more easily. If you think you have an infection, have a fever, or feel like you have the flu during and up to 2 months after stopping treatment, call your doctor.



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



Liver function—GILENYA® (fingolimod) can cause abnormal results in liver function tests. You will need a blood test prior to treatment initiation and at months 1, 3, 6, 9, and 12 during GILENYA therapy and regularly thereafter.



Pregnancy—You need to have a negative pregnancy test before taking GILENYA. You should avoid becoming pregnant while taking GILENYA and in the 2 months after you stop taking the treatment because there is a risk of harm to the baby. Talk with your doctor about reliable methods of birth control that you should use during treatment and for 2 months after you stop treatment. Immediately report to your doctor any (intended or unintended) pregnancy during and for 2 months following discontinuation of treatment with GILENYA.

If you need to see other doctors, remember to tell them that you are taking GILENYA.

For more information please refer to the Package Leaflet



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