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 fingolimod. If the doctor considers that there is benefit for you to be treated with fingolimod, additional care and monitoring, including overnight stay, may be required.

The first time you take Gilenya (fingolimod)

Slow heart rate and irregular heartbeat – At the beginning of treatment, fingolimod 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 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

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 Fingolimod 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 fingolimod 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 (fingolimod)

Infections – While you are taking fingolimod, you may get infections more easily. If you think you have an infection, have fever, feel like you have the flu, or have a headache accompanied by stiff neck, sensitivity to light, nausea, and/or confusion (these may be symptoms of meningitis), during and up to 2 months after stopping treatment, call your doctor straight away.

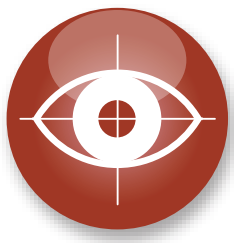
If you believe your MS is getting worse (e.g. weakness or visual changes) or if you notice any new symptoms, talk to your doctor as soon as possible, because these may be the symptoms of a rare brain disorder caused by infection and called progressive multifocal leukoencephalopathy (PML).

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 Fingolimod therapy and regularly thereafter.

Pregnancy – You need to have a negative pregnancy test before taking fingolimod. You should avoid becoming pregnant while taking fingolimod 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 fingolimod.

Skin growth – A type of skin cancer called basal cell carcinoma (BCC) has been reported in MS patients treated with Gilenya (fingolimod). Talk to your doctor if you notice any skin nodules (e.g. shiny pearly nodules), patches or open sores that do not heal within weeks (these may be signs of BCC).

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



Visual symptoms – Fingolimod 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.

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:

Medicines Authority Post-licensing Directorate, 203, Level 3, Rue D'Argens, Gzira GZR 1368, MALTA or at: www.medicinesauthority.gov.mt/adrportal

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

NOVARTIS PHARMACEUTICALS

Marketing Authorisation Holder: Novartis Europharm Limited, Frimley Business Park, Camberley GU16 7SR, United Kingdom

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

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