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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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.

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

The first time you take Gilenya (fingolimod)

Slow heart rate and irregular heartbeat –

At the beginning of treatment, fingolimod may cause 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

The first time you take Gilenya (fingolimod)

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 – Because fingolimod affects the immune system, you are more likely to get infections. If you think you have any of the following, during and up to two months after stopping treatment, call your 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 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 (fingolimod)

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 use effective contraception whilst taking fingolimod, and in the two months after you stop taking the treatment because there is a risk of harm to the unborn baby. Immediately report to your doctor any (intended or unintended) pregnancy during and for two months following discontinuation of treatment with fingolimod.

While you are taking Gilenya (fingolimod)

Skin cancer – Skin cancers have been reported in MS patients treated with Gilenya (fingolimod). Talk to your doctor straight away 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 colour, shape or size over time.

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 two months after treatment.

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.

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.

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