Important things to remember about Gilenya® (fingolimod) ▼ treatment

For parents and caregivers

▼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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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.

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

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

The first time they 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 they 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 at least 1 day or more during the first 2 weeks of treatment, or 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 more than a 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 they 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 two 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 they are taking 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.

Skin cancer – Skin cancers have been reported in MS 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.

While they are taking Gilenya

Liver function – Gilenya can cause abnormal results in liver function tests. The child/adolescent 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 – Adolescent females of childbearing potential need to have a negative pregnancy test before starting treatment because of the serious risks of Gilenya to the fetus.

The adolescent should use effective contraception whilst taking Gilenya, and in the two months after stopping taking the treatment because there is a risk of harm to the unborn baby.

Immediately report to their doctor any (intended or unintended) pregnancy during and for two months following discontinuation of treatment with Gilenya.

While they 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 two months after stopping treatment.

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.

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.

Notes:

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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