

Contact your doctor, pharmacist or nurse if you experience any side effects during treatment with fingolimod. This includes any possible side effects not listed in the Package Leaflet. You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

You can also report side effects directly to Mylan IRE Healthcare Limited using the following contact details: pv.ireland@viatris.com

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Fingolimod Mylan 0.5 mg hard capsules Patient/Parent/Caregiver's guide

**Important things to remember about
your fingolimod treatment**

About this guide

- This guide contains important safety information about fingolimod for patients and their parents or caregivers. If you are a parent or caregiver of a patient, please read 'you' as referring to the child/ person for whom you are caring.

It is important to also read the Package Leaflet provided with your medication (or also available at www.hpra.ie) for full information on fingolimod. Please retain this guide and the Package Leaflet in case you need to refer to them during your treatment.

What is multiple sclerosis?

- Multiple sclerosis (MS) is a long-term autoimmune condition that affects the central nervous system (CNS) comprised of the brain and spinal cord. In MS, the immune system mistakenly attacks the protective myelin sheath around the nerves in the CNS and stops the nerves from working properly.

- Relapsing-remitting MS is characterized by repeated attacks (relapses) of nervous system symptoms that reflect inflammation within the CNS. Symptoms vary from patient to patient but typically involve walking difficulties, numbness, vision problems or disturbed balance. Symptoms of a relapse may disappear completely when the relapse is over, but some problems may remain.

How does fingolimod work?

- Fingolimod helps to protect against attacks on the CNS by the immune system by reducing the ability of some white blood cells (lymphocytes) to move freely within the body and by stopping them from reaching the brain and spinal cord. This limits nerve damage caused by MS. This medicine also reduces some of the immune reactions of your body.

Safety information for before, during and after fingolimod treatment

- 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.
- Your doctor will ask you to stay at the hospital 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 repeated for children if their dose is increased from 0.25mg to 0.5mg.
- **Fingolimod can seriously harm an unborn baby. You must not take fingolimod if you are pregnant, trying to become pregnant or a woman of childbearing potential (including adolescent) not using effective contraception.**

- Please inform your doctor if you or a family member have a history of epilepsy.
- Contact your doctor immediately if you are pregnant or if you experience any side effects during treatment with fingolimod and up to two months following discontinuation.
- Any doctors that you see should be told that you are taking fingolimod.

Before starting fingolimod treatment

- **Human papilloma virus (HPV)-related cancer** – Your doctor will assess whether you need to undergo cancer screening (including a Pap test) and if you should receive the HPV vaccine.
- **Liver function** – Fingolimod can cause abnormal results in liver function tests. You will need a blood test before starting treatment with fingolimod.
- **Seizures** – Seizures may occur during treatment. Inform your doctor if you or a family member have a history of epilepsy.

Pregnancy prevention for women and girls of childbearing potential

- Fingolimod can seriously harm an unborn baby. You must not take fingolimod if you are pregnant, trying to become pregnant or a woman of childbearing potential (including adolescent) not using effective contraception
- Your doctor will inform you about the serious risks of fingolimod to an unborn baby and will explain what you need to do to avoid becoming pregnant whilst taking fingolimod.
- You must have a negative pregnancy test and must use effective contraception before starting treatment with fingolimod.
- Your doctor will provide you with a 'Fingolimod pregnancy-specific patient reminder card'. Please read this and retain it so that you can refer to it during treatment.

The first time you take 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, vertigo, nausea or palpitations, or feel uncomfortable after taking the first dose of fingolimod, please inform your doctor immediately.

Before you take the first dose, you will have:

- A baseline electrocardiogram (ECG) to assess the action of your heart
- A blood pressure measurement
- Children and adolescents will also be weighed and measured, and will undergo a physical development assessment.

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 forget to take fingolimod:

It is important to ensure medication compliance and to avoid misuse, especially treatment interruptions. If you miss doses, your doctor may need to repeat the cardiac monitoring you had with the first dose as the initial effect on heart rate may occur again. Call your doctor in case of treatment interruption if you have stopped treatment for:

- 1 or more days during first 2 weeks of treatment
- Or more than 7 days during weeks 3 and 4 of treatment
- Or more than 2 weeks after one month on treatment
- Never take a double dose to make up for a forgotten dose.

While you are taking fingolimod

- **Infections** – Because fingolimod affects the immune system, you are more likely to get infections.

Seek urgent medical attention if you develop any of the following during fingolimod treatment and for 2 months after the last dose: headache accompanied by stiff neck, sensitivity to light, fever, flu-like symptoms, nausea, rash, shingles and/or confusion or seizures (fits) (these may be symptoms of meningitis and/or encephalitis, either caused by a fungal or viral infection).

Progressive Multifocal Leukoencephalopathy (PML) is a rare brain infection which may result in severe disability or death. The symptoms of PML may be similar to a MS relapse and can include clumsiness, weakness, difficulty thinking or speaking and changes in behaviour and vision. Contact your doctor as soon as possible if you think your MS is getting worse or if you notice any new neurological symptoms during fingolimod treatment and for 2 months after the last dose.

- **Skin cancer** – Skin cancers have been reported in multiple sclerosis patients treated with fingolimod. 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 colour, shape or size over time.
- **Liver function** – Fingolimod can cause abnormal results in liver function tests. Some cases of liver failure requiring liver transplant and clinically significant liver injury have been reported. You will need a blood test at months 1, 3, 6, 9, and 12 during fingolimod therapy and regularly thereafter until 2 months after you finish treatment. Inform your doctor if you notice any of the following: yellowing of the skin or the whites of the eyes, abnormally dark urine, pain on the right side of the stomach area, tiredness, feeling less hungry than usual or unexplained nausea and vomiting. These can be signs of liver injury.
- **Pregnancy prevention for women of childbearing potential** – Women of childbearing potential (including adolescents) must have pregnancy tests repeated at suitable intervals during fingolimod treatment. You must use effective contraception whilst taking fingolimod, and in the 2 months after you stop taking the treatment because of fingolimod's serious risks to the foetus.

You should receive regular counselling from a healthcare professional about the serious risks of fingolimod to the unborn baby.

Immediately report to your doctor any (intended or unintended) pregnancy during and for 2 months following discontinuation of treatment with fingolimod

You should tell your doctor if you are planning a pregnancy so that your treatment can be altered.

- **Visual symptoms** – Fingolimod may cause swelling at the back of the eye, a condition that is known as macular oedema. Contact your doctor immediately if you experience visual symptoms during and up to 2 months after stopping treatment.
- **Seizures** – Seizures may occur during treatment. Inform your doctor if you or a family member have a history of epilepsy.
- **Depression and anxiety** – Depression and anxiety are known to occur with increased frequency in the MS population and have also been reported in paediatric patients treated with fingolimod. Talk to your doctor if you are experiencing symptoms.
- **Possible return of symptoms after stopping treatment** – Stopping fingolimod therapy may result in return of disease activity. Your doctor will decide whether and how you need to be monitored after stopping fingolimod.