They should be provided with regular counselling about fingolimod's serious risks to an unborn baby by their doctor.

In case of pregnancy (intended or unintended) during treatment, or in the 2 months after stopping treatment with fingolimod, the doctor should be informed straight away.

Visual symptoms-
Fingolimod may cause swelling at the back of the eye, a condition that is known as macular oedema. Tell the doctor if you or the child/adolescent in your care experiences any changes in vision during and up to 2 months after stopping treatment.

Seizures -
Seizures may occur during treatment. Inform the doctor if you or the child/adolescent in your care, or someone related to them, has 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 or the child/adolescent in your care are experiencing symptoms.

Stopping fingolimod-
Stopping fingolimod therapy may result in return of disease activity. Your doctor will decide whether and how you or the child/adolescent need to be monitored after stopping fingolimod.

Reporting side effects

If you get any side effects, talk to your prescriber, pharmacist or nurse. This includes any possible side effects not listed in this brochure.

You can also report side effects directly via the HPRA Pharmacovigilance website: www.hpra.ie . By reporting side effects, you can help provide more information on the safety of this medicine.

Side effects should also be reported to Tillomed on below contact details:

Telephone/Email: Call the Medical Information department at +44 (0)800 9706115 or email at medical.information@tillomed.com

Please see the "Patient Information Leaflet" for more information.

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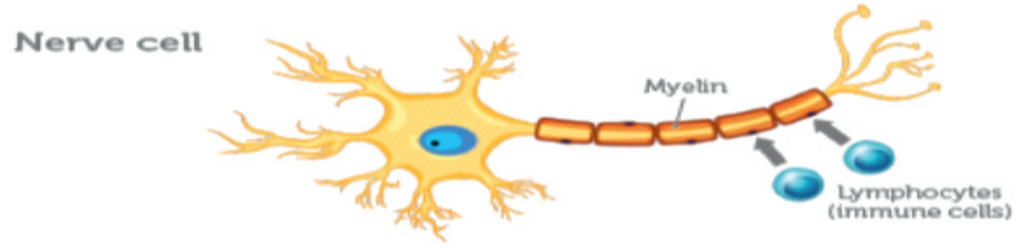
Fingolimod Tillomed (fingolimod)
Patient/Parent/Caregiver Guide

Important things to remember about fingolimod treatment for patients, parents and caregivers

What is multiple sclerosis (MS)?

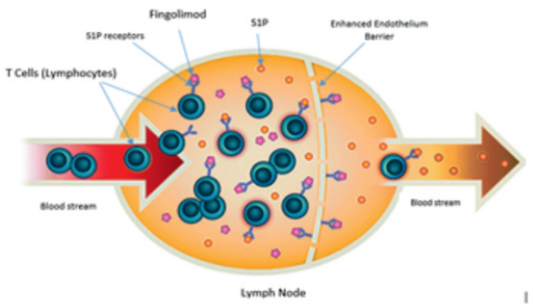
MS is a long-term autoimmune condition that affects the central nervous system (CNS), comprised of the brain and spinal cord. In MS, the immune system mistakenly attacks the protective myelin sheath around the nerves in the CNS and stops the nerves from working properly.

Relapsing-remitting MS is characterised 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?

Your immune system normally fights infections to prevent illnesses. However, if you have MS it can become overactive and attack the myelin that protect the neurons and help them to carry messages from your brain to the rest of your body.



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 can reduce the neural damage caused by MS.

Contraindications and precautions

The doctor will ask the person who has been prescribed fingolimod, to stay at the clinic for 6 hours or more 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.

- 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.
- Fingolimod must not be used in women who are pregnant and women of childbearing potential (including female adolescents) not using effective contraception.

- If you are a woman of childbearing potential or the parent/caregiver of a female adolescent of childbearing potential prescribed fingolimod, you will be provided with a Pregnancy-Specific Patient Reminder Card

Contraindications and precautions

- Please read the Patient Information Leaflet thoroughly before you or the child/adolescent in your care starts treatment with fingolimod. The Patient Information Leaflet should be retained so you can refer to it throughout treatment.
- Please inform the doctor if the individual taking fingolimod, or anyone related to them, has a history of epilepsy.
- Contact your doctor immediately if you or the child/adolescent in your care experiences any adverse reactions during treatment with fingolimod.
- Any doctors that you or the child/adolescent in your care sees should be told you/they are taking fingolimod

Before starting Fingolimod treatment

Pregnancy

Fingolimod is teratogenic (can harm an unborn baby).

Fingolimod must not be taken by pregnant women or by women of childbearing potential not using effective contraception.

Women of childbearing potential (including female adolescents) should be informed by their doctor about fingolimod's serious risks to the unborn baby and must have a negative pregnancy test and be using effective contraception before starting treatment with fingolimod.

Talk to your doctor about appropriate forms of effective contraception.

All women of childbearing potential (including adolescents) will be provided with a Pregnancy-Specific Patient Reminder Card

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 or the child/adolescent in your care will need a blood test prior to treatment initiation with fingolimod.

Seizures

Seizures may occur during treatment. Inform the doctor if the individual taking fingolimod or anyone related to them has a history of epilepsy

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 cause dizziness or lower the blood pressure. If the individual taking fingolimod experiences symptoms such as dizziness, nausea, vertigo, or palpitations or feels uncomfortable after taking the first dose of fingolimod, please immediately inform their doctor.

Before you take the first dose, you or the child/adolescent will have:

- A baseline electrocardiogram (ECG) to assess the action of their heart
- A blood pressure measurement

- A physical development assessment (child/ adolescent patients only)
- Height and weight measurements (child/ adolescent patients only)

During the 6-hour monitoring, you will have:

- Pulse and blood pressure checked every hour
- An ECG at the end of 6 hours

– You or the child/adolescent may also be monitored with a continuous ECG during this time

It is important to ensure medication compliance and avoid misuse especially treatment interruption which may result in a requirement to repeat cardiac monitoring. Call the doctor in case of treatment interruption if you or the child/adolescent has stopped fingolimod for at least:

- 1 day or more 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

as the initial effect on your heart rate may occur again. When fingolimod therapy is restarted, the doctor may decide to repeat monitoring of heart rate and blood pressure measurements every hour, to run ECGs, and if needed, to monitor you or the child/adolescent overnight.

While you are taking Fingolimod

Infections-

Because fingolimod affects the immune system, those treated with it are more likely to get infections.

If the individual taking fingolimod has any of the following, during and up to 2 months after stopping treatment, call their doctor straight away: a headache accompanied by a stiff neck, sensitivity to light, fever, flu-like symptoms, nausea, rash, shingles and or/confusion or seizures (fits) (possible symptoms of meningitis and/or encephalitis, either caused by fungal or viral infection).

If you believe your MS or that of the child/adolescent in your care 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 caused by an infection.

Cancer -

The doctor will assess whether an individual taking fingolimod needs to undergo cancer screening (including a Pap test), and if they should receive the human papilloma virus (HPV) vaccine.

Skin cancer-

Skin cancers have been reported in MS 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-

Some cases of acute liver failure requiring liver transplant and clinically significant liver injury have been reported. A blood test to assess liver function will be required at months 1,3,6,9 and 12 during fingolimod therapy and regularly thereafter until 2 months after fingolimod discontinuation. Inform the doctor if you notice any 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 as these can be signs of liver injury.

Pregnancy-

Women of child-bearing potential (including female adolescents) must use effective contraception while taking fingolimod and for two months after stopping treatment, because of the serious risks of fingolimod to the unborn baby.