Patient, Parent and Caregiver Guide

Important things to know about Fingolimod Teva treatment.

For further information, please contact Teva UK Limited Scientific service team on 0207 540 7117 or medinfo.Teva@tevauk.com

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Introduction

Please read the Patient Information Leaflet thoroughly before starting treatment with fingolimod. Consider keeping the Patient Information Leaflet in case you need to refer to it during your 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. If any of this applies to you, you should tell your doctor before taking fingolimod.

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. Children aged 10 years or older should also be similarly monitored if their dose is increased from 0.25 mg to 0.5 mg once daily.

Fingolimod should not be used in women who are pregnant or in women of child-bearing potential (including adolescents) if they are not using effective contraception.

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

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.

Please inform your doctor if you or a family member have a history of epilepsy.

Important things to discuss with your doctor before starting fingolimod

Fingolimod must not be used in pregnant women or in women who could become pregnant if they are not using effective contraception, including adolescents.

If there is a chance of becoming pregnant, your doctor should explain the serious risks fingolimod can pose to an unborn baby.

If you are a woman of child-bearing potential, you or your caregiver will be provided with a Pregnancy-Specific Patient Reminder Card.

Inform your doctor if you have underlying heart conditions or if you are taking medicines that are known to decrease heart rate.

Fingolimod affects the immune system, inform your doctor if you have symptoms of an infection.

Inform your doctor if you have liver problems.

Screening tests to determine if fingolimod is suitable for you

Before taking the first dose, you will have:

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

Liver function tests will be taken prior to treatment initiation as fingolimod can cause abnormal results in liver function tests and liver injury.

Blood counts will be performed prior to starting treatment with fingolimod.

Your doctor may arrange an eye assessment before starting fingolimod as well as a follow-up eye assessment 3-4 months after starting treatment.

For women of child-bearing potential, a pregnancy test must be carried out and negative results verified by your doctor before starting treatment.

Your doctor will arrange magnetic resonance imaging (MRI) scans before you start treatment and during treatment to monitor the risk of progressive multifocal leukoencephalopathy (PML).

Taking fingolimod for the first time

At the beginning of treatment, fingolimod causes the heart rate to slow down.

Immediately inform your doctor if you experience any symptoms such as dizziness, nausea, vertigo, or palpitations which may be signs of a low heart rate after taking your first dose of fingolimod.

Your doctor will ask you to stay at the 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.

During the 6-hour monitoring, you will have your pulse and blood pressure checked every hour and you may be monitored with continuous ECG during this time. You will also have an ECG at the end of 6 hours.

While taking fingolimod

Please remember to contact your doctor immediately if you experience side effects.

Tell any healthcare professional treating you that you are taking fingolimod.

Treatment Interruptions:

Call your doctor in case of missed doses as the first dose monitoring may need to be repeated.

Visual Symptoms:

Fingolimod may cause swelling at the back of the eye (macular oedema).

Immediately inform your doctor of any symptoms of visual changes during treatment and for up to two months after the end of treatment with fingolimod.

While taking fingolimod

Infections:

Because fingolimod affects the immune system, people taking fingolimod are more likely to get infections.

If you have any of the following, during and up to 2 months after stopping treatment, call your doctor immediately:

- a headache accompanied by a stiff neck,
- sensitivity to light,
- fever,
- flu symptoms,
- nausea,
- rash,
- shingles and/or confusion or seizures (fits) (possible symptoms of meningitis and/or encephalitis).

Your doctor will monitor your white blood cell (lymphocyte) counts during treatment with fingolimod. Treatment with fingolimod may be interrupted if your lymphocyte count is too low.

While taking fingolimod

Inform your doctor immediately if you believe your multiple sclerosis (MS) is getting worse or if you notice any new symptoms, during and after treatment with fingolimod, for example:

- changes in mood or behaviour,
- new or worsening weakness on one side of the body,
- changes in vision,
- confusion,
- memory lapses,
- speech and communication difficulties.

These may be the symptoms of progressive multifocal leukoencephalopathy (PML is a rare brain disorder caused by an infection that may lead to severe disability or death) or of an inflammatory reaction (known as immune reconstitution inflammatory syndrome or IRIS) that can occur in patients with PML as fingolimod is removed from their body after they stop taking it. Your doctor will arrange MRI scans during treatment to monitor the risk of PML.

Tell your partner or carers about the risks of fingolimod so they can report any symptoms that you may not be aware of.

While taking fingolimod

Skin cancers have been reported in MS patients treated with fingolimod. Inform your doctor immediately if you notice any skin lump, red 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.

Speak to your GP immediately if you have any symptoms of skin cancer or are worried about any abnormal areas of skin.

Some cases of liver failure requiring liver transplant and clinically significant liver injury have been reported. After starting fingolimod, you will need a blood test at months 1, 3, 6, 9, and 12, and regularly thereafter while on treatment until 2 months after fingolimod discontinuation. Inform your doctor immediately if you notice:

- yellowing of your skin or the whites of your eyes,
- abnormally dark urine,
- pain on the right-hand side under your ribs,
- unexplained nausea and vomiting.

These can be signs of liver injury and you should seek urgent medical attention.

While taking fingolimod

Women of child-bearing potential must have pregnancy tests repeated at suitable intervals during fingolimod treatment.

Women of child-bearing potential must receive regular counselling from a healthcare professional facilitated by the Pregnancy-Specific Patient Reminder Card about the serious risks of fingolimod to the foetus.

Women of childbearing potential must use effective contraception whilst taking fingolimod, and in the 2 months after you stop taking the treatment because of the serious risks to the unborn baby caused by fingolimod.

Contact your doctor immediately if you become pregnant during fingolimod treatment or in the 2 month period after stopping it.

Use in children aged 10 years or more and adolescents

For children aged 10 years or more and adolescents, in addition to the screening tests listed, their doctor will also assess:

- Height and weight
- Puberty status
- Vaccination status

6-hour monitoring (or similar precautions) will also be taken when the dose is increased from 0.25 mg to 0.5 mg once daily.

Both depression and anxiety have been reported in children and adolescents treated with fingolimod. If the child or adolescent in your care is experiencing symptoms, talk to their doctor.

Reporting side effects

If you get side-effects with any medication you are taking, talk to your doctor, pharmacist or nurse.
This includes any possible side effects not listed in the information leaflet that comes in the pack.

Please report suspected side effects to the MHRA through the Yellow Card scheme.
You can report via:

- the Yellow Card website www.mhra.gov.uk/yellowcard
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively you can report a side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.

When reporting please provide as much information as possible. By reporting side effects,
you can help provide more information on the safety of this medicine.

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