Fingolimod Teva patient information

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

You can help by reporting any side effects you may get.
See www.mhra.gov.uk/yellowcard for how to report side effects.

Adverse events should be reported to Teva UK Limited Medical Information *via* phone on 0207 540 7117 or *via* email to medinfo@tevauk.com

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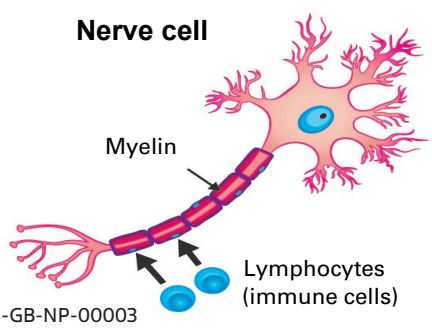
What is multiple sclerosis (MS)?

MS is a long-term autoimmune condition that affects the central nervous system (CNS). 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.

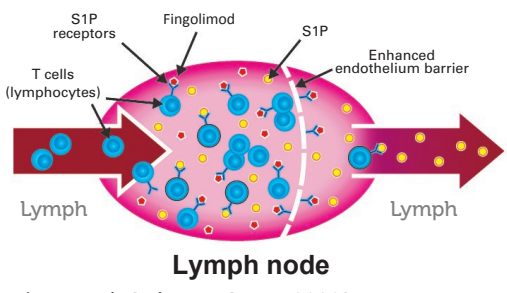


How does fingolimod work?

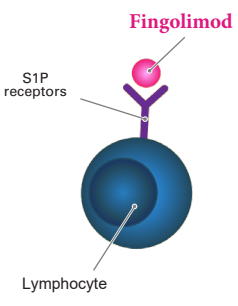
It is not fully understood how fingolimod therapy works in MS.

Fingolimod binds to sphingosine-1-phosphate (S1P) receptors on lymphocytes (a type of blood cell involved in the immune system). Once lymphocytes have bound to fingolimod, they are unable to leave lymph nodes (glands) and in turn are unable to enter blood vessels. Through this mechanism of action, fingolimod reduces the numbers of lymphocytes in the blood and prevents immune reactions including inflammation in the brain and spinal cord.

The effects of fingolimod may persist for up to 2 months after you stop taking it.



Lymph node



Introduction

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 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.

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.

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

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.

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.

Before starting fingolimod treatment

Pregnancy

Fingolimod is teratogenic (causes defects to unborn babies). Women of child-bearing potential (including adolescents) should be informed by their doctor about fingolimod's serious risks to the foetus, they must have a negative pregnancy test (checked by a healthcare professional), and must take effective contraception before starting treatment with fingolimod. Consider speaking to your doctor about appropriate forms of effective contraception.

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 prior to treatment initiation with fingolimod.

Seizures

Seizures may occur during treatment. Inform your doctor if you or a family member have 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 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

Children aged 10 years or older 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

Call your doctor if you have missed any doses of fingolimod as the first dose monitoring may need to be repeated depending on how many doses you have missed and the duration of fingolimod treatment.

While you are taking 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 2 months after stopping treatment, seek urgent medical attention: a headache accompanied by a 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 fungal or viral infection).

Fingolimod can cause a serious viral infection called progressive multifocal leukoencephalopathy (PML). The symptoms of PML may be similar to an MS relapse and can include changes in mental ability or behaviour, unsteadiness, limb or facial weakness and visual changes. 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. You will need a blood test at months 1, 3, 6, 9, and 12 during fingolimod therapy and regularly thereafter until 2 months after fingolimod discontinuation.

Inform your doctor straight away if you notice any of the following: yellowing of your skin or the whites of your 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.

While you are taking fingolimod (continued)

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.

Depression and anxiety

Depression and anxiety are known to occur with increased frequency in the multiple sclerosis population and have also been reported in children aged 10 years or older treated with fingolimod. Talk to your doctor if you are experiencing symptoms.

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.

Pregnancy

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

You should receive regular counselling from a healthcare professional about the serious risks of fingolimod to the unborn baby and the need for effective contraception. This counselling will be based on the information contained in the Pregnancy-Specific Patient Reminder Card. You also should tell your doctor if you are planning a pregnancy so that your treatment can be altered.

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.

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

Reporting of 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 adverse drug reactions (ADRs) 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 suspected 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

All adverse events and pregnancies should be reported to Teva UK Limited Medical Information *via* **medinfo@tevauk.com** or **0207 540 7117**.

Teva UK Limited Medical Information

Tel No: **0207 540 7117**
Email: **medinfo@tevauk.com**

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