



**MARCAN**  
PATIENT SUPPORT  
PROGRAMS

IMPORTANT  
THINGS TO REMEMBER ABOUT  
**MAR-FINGOLIMOD** TREATMENT  
FOR PATIENTS, PARENTS  
AND CAREGIVERS

**MARCAN**

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## • INTRODUCTION

You have been prescribed Fingolimod for your multiple sclerosis. Fingolimod is not recommended in patients with specific cardiac diseases or those taking medicines that are known to decrease heart rate.

Please tell your doctor about such conditions before being treated with Fingolimod. If the doctor considers that there is benefit for you to be treated with Fingolimod, additional care and monitoring, including overnight stay, may be required.

Please inform your doctors if you or a family member have a history of epilepsy. Taking Fingolimod with St John's wort is not recommended.

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html> for how to report side effects.

For further information please contact Medical Information: 1-855-627-2261 or [safety.canada@marcanpharma.com](mailto:safety.canada@marcanpharma.com).

## • TAKING FINGOLIMOD FOR THE FIRST TIME

Your doctor will ask you to stay at the surgery or clinic for 6 or more hours after taking the first dose so that appropriate measures can be taken if side effects occur.

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 tell any doctor you see that you are taking Fingolimod.

Fingolimod is not recommended for use in children.

## • 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
- A pregnancy test
- A blood test.

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.

In some circumstances, an overnight stay may be required.

Call your doctor in case of treatment interruption. If you have stopped Fingolimod for at least 1 day during your first 2 weeks of treatment, if you have stopped Fingolimod for more than 7 days during weeks 3 and 4 of treatment, or if you have stopped Fingolimod for more than 2 weeks after you have been on treatment for more than a month, the initial effect on your heart rate may occur again. When you restart your Fingolimod therapy, your doctor may decide to monitor your heart rate and blood pressure measurements every hour, to run ECGs, and, if needed, to monitor you overnight.

## - WHILE YOU ARE TAKING MAR-FINGOLIMOD

### INFECTIONS

While you are taking Fingolimod, you may get infections more easily because Fingolimod affects the immune system. If you think you have an infection, have a fever, feel like you have the flu, or have a headache accompanied by a stiff neck, sensitivity to light, nausea, and/or confusion (these may be symptoms of meningitis) during and up to 2 months after stopping treatment, call your doctor immediately.

If you believe your multiple sclerosis is getting worse (e.g. weakness or visual changes) or notice any new symptoms, talk to your doctor as soon as possible because these may be the symptoms of a rare brain disorder caused by infection and called progressive multifocal leukoencephalopathy (PML).

### VISUAL SYMPTOMS

Fingolimod may cause swelling at the back of the eye, a condition that is known as macular edema. Tell your doctor immediately about any changes in your vision during and up to 2 months after stopping treatment.

### BLOOD TESTS

Fingolimod can cause abnormal results in liver function tests. You will need a blood test prior to treatment initiation and at months 1, 3, 6, 9, and 12 during Fingolimod therapy and regularly thereafter.

A full blood count (FBC) will be required before initiation, at 3 months, and yearly thereafter.

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.

## SKIN CANCER

Skin cancer has been reported in multiple sclerosis patients treated with Fingolimod. Talk to your doctor straight away 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.

## PREGNANCY

You need to have a negative pregnancy test before taking Fingolimod. Women of child-bearing age, including female adolescents, should avoid becoming pregnant while taking Fingolimod and in the 2 months after stopping treatment because there is a risk of harm to the unborn baby. Talk with your doctor about reliable methods of birth control that you should use during treatment and for 2 months after you stop treatment.

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

All pregnancies should be reported to Marcan through [safety.canada@marcanpharma.com](mailto:safety.canada@marcanpharma.com) or 1-855-627-2261.

## STOPPING FINGOLIMOD

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.

If you need to see any doctor, nurse, dentist or pharmacist, remember to tell them you are taking Fingolimod.

## 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.

You can also report the side effect. It is easiest and quickest to report side effects online via the Canada Vigilance website

<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>

Submit by:

Telephone: Call the Canada Vigilance National Office at 1-866-234-2345 (toll-free).

By reporting side effects you can help provide more information on the safety of your medication.