



# Gemorya Patient Information Booklet

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA.

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Confidential

## What is multiple sclerosis (MS)?

Multiple Sclerosis (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 8 weeks after you stop taking it.

## 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.
- 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 before starting 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

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Because Fingolimod affects the immune system, you are more likely to get infections. Seek urgent medical attention if you develop any symptoms of an infection, including flu and meningitis (may cause a raised temperature, rash, stiff neck, sensitivity to light, nausea, and confusion), during Fingolimod treatment and for 8 weeks after the last dose. 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 behavior, 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 8 weeks 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 color, 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.

#### **- 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. 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 Side Effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet.

### **The National Pharmacovigilance & Drug safety Centre (NPC)**

Saudi Food and Drug Authority (SFDA)

- Fax: +966-11-205-7662
- SFDA Call Center: 19999
- E-mail: [npc.drug@sfd.a.gov.sa](mailto:npc.drug@sfd.a.gov.sa)
- Website: <https://ade.sfda.gov.sa/>

### **Company Contact Information**

#### **Pharmacovigilance Representative**

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