

Fingolimod Dr.Reddy's

Patient's, Parent's and Caregiver's Guide

▼ This medicinal product is subject to additional monitoring in Australia. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Contents

1. Overview	3
1.1 What is Multiple sclerosis	3
1.2 How does Fingolimod Dr.Reddy's work?	4
2 Before starting Fingolimod Dr.Reddy's	4
3 First time you take Fingolimod Dr.Reddy's	6
4 During the treatment with Fingolimod Dr.Reddy's	7
5 Reporting Of Adverse Events	9

1. Overview

This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.

Fingolimod Dr.Reddy's (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 Dr.Reddy's 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 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 Dr.Reddy's and up to two months following discontinuation.

1.1 What is 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 characterized 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.

1.2 How does Fingolimod Dr.Reddy's 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.

2 Before starting Fingolimod Dr.Reddy's

Before you start treatment, you will have:

Eye test - An eye examination before you start treatment and at regular intervals afterwards is recommended if you have or have had one of the following conditions:

- visual disturbances or other signs of swelling in the central vision area at the back of the eye (a condition known as macular oedema)
- inflammation or infection of the eye (uveitis)
- diabetes

Cardiovascular check - 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.

Vaccination - Children and adolescents should complete their vaccinations. Adults should get checked for antibody status and receive vaccinations if required.

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 Dr.Reddy's. 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 Dr.Reddy's.

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

3 First time you take Fingolimod Dr.Reddy's

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 Dr.Reddy's, 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 Dr.Reddy's as the first dose monitoring may need to be repeated depending on how many doses you have missed and the duration of Fingolimod treatment.

4 During the treatment with Fingolimod Dr.Reddy's
Infections

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 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 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 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 and until two months after stopping treatment. If liver problems are detected your doctor may decide to discontinue treatment.

Signs and symptoms of liver injury - unexplained nausea, vomiting, abdominal pain - pain on the right side of your stomach area, yellowing of the skin or whites of your eyes, abnormally dark urine, feeling less hungry than usual and tiredness.

Inform the doctor straight away if any of the signs/symptoms are noticed.

Some side effects may not give you any symptoms and can only be found when tests are done. These include:

- higher levels of liver enzymes and/or liver injury

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 Dr.Reddy's therapy may result in return of disease activity. Your doctor will decide whether and how you need to be monitored after stopping Fingolimod Dr.Reddy's.

Pregnancy

Women of child-bearing potential (including adolescents) must have pregnancy tests repeated at suitable intervals during Fingolimod Dr.Reddy's treatment.

You should receive regular counselling from a healthcare professional about the serious risks of Fingolimod Dr.Reddy's 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 Dr.Reddy's, 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 Dr.Reddy's.

If you need to receive a vaccine, seek your doctor's advice first. During and up to 2 months after treatment with Fingolimod, administration of some vaccines containing live virus (live attenuated vaccines) may result in an infection that the vaccination is designed to prevent, while others may not work as well.

5 Reporting Of Adverse Events

The safe use of Fingolimod is of paramount importance. As part of the ongoing safety monitoring, Dr. Reddy's Laboratories wishes to learn of Adverse Events that have occurred during the use of Fingolimod.

For reporting an adverse events please contact Dr. Reddy's Laboratories

DR. REDDYS' LABORATORIES CONTACT DETAILS

Tel: 1800 733 397

Email: ds@commercialeyes.com.au

Please report suspected adverse drug reactions (ADRs) to the Therapeutic Goods Administration (TGA) website www.tga.gov.au/reporting-problems.

Note:

- The CMI will be available inside each pack.
- If the patient needs to see other doctors, they must tell their doctor that they are taking fingolimod.