

Fingolimod Accord

Important things for Patients, Parents and
Caregivers to remember about Fingolimod
Accord treatment

What is multiple sclerosis (MS)?

MS is a long-term condition that affects the central nervous system (CNS), comprised of the brain and spinal cord. In MS, inflammation destroys the protective sheath (called myelin) around the nerves in the CNS and stops the brain cells (neurons) from working properly. This is called demyelination.

Relapsing-remitting MS is characterised by repeated attacks (relapses) that reflect inflammation within the CNS. Symptoms vary from patient to patient. Symptoms of a relapse may disappear completely when the relapse is over, but some problems may remain.

How does Fingolimod Accord work?

Your immune system normally fights infections to prevent illnesses. However, if you have MS it can become overactive and attack the myelin that protect the neurons and help them to carry messages from your brain to the rest of your body.

Fingolimod Accord helps to protect against attacks on the CNS by the immune system by reducing the ability of some white blood cells (lymphocytes) to move freely within the body and by stopping them from reaching the brain and spinal cord. This can reduce the neural damage caused by MS.

Contraindications and precautions

The doctor will ask the person who has been prescribed Fingolimod Accord, to stay at the clinic for 6 hours or more 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. Similar precautions will be taken if their dose is increased from 0.25 mg to 0.5 mg once daily.

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 and women of child-bearing potential (including female adolescents) not using effective contraception.

If you are a woman of child-bearing potential or the parent/caregiver of a female adolescent of child-bearing potential prescribed Fingolimod Accord, you will be provided with a Pregnancy-Specific Patient Reminder Card.

Please inform the doctor if the individual taking Fingolimod or anyone related to them, has a history of epilepsy.

Contact your doctor immediately if you or the child/adolescent in your care experiences any adverse reactions during treatment with Fingolimod.

Any doctors that you or the child/adolescent in your care sees should be told they are taking Fingolimod.

Before starting Fingolimod Accord treatment

Pregnancy— Fingolimod can harm an unborn baby (the medicine is said to be ‘teratogenic’). Women of child-bearing potential (including female adolescents) should be informed by their doctor about Fingolimod’s serious risk to the unborn baby. Women of child-bearing potential (including female adolescents) should have a negative pregnancy test and be using effective contraception before starting treatment with Fingolimod.

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 or the child/adolescent in your care will need a blood test prior to treatment initiation with Fingolimod.

Seizures – Seizures may occur during treatment. Inform your doctor if the individual taking Fingolimod or a family member have a history of epilepsy.

The first time you take Fingolimod Accord

Slow heart rate and irregular heartbeat — At the beginning of treatment, Fingolimod causes the heart rate to slow down. This may cause dizziness or lower the blood pressure. If you or the child/adolescent in your care experiences symptoms such as dizziness, nausea, vertigo, or palpitations or feel uncomfortable after taking the first dose of fingolimod, please immediately inform the doctor.

Before taking the first dose, you or the child/adolescent will have:

- A baseline electrocardiogram (ECG) to assess the action of your or their heart.
- A blood pressure measurement.
- A review of medication you or they are taking
- Blood tests to assess your or their white blood cell count, immunity against the virus that causes chickenpox and liver function
- A pregnancy test to ensure that you or they are not pregnant because of the serious risks of Fingolimod to the foetus
- A cardiovascular assessment, especially if you or they have a history of heart problems
- An eye examination, especially if you or they have or have had eye conditions or diabetes

Pediatric patients will also be weighed and measured, and will undergo a physical development assessment and an immunization status check.

After you or the child/adolescent have taken the first dose, the doctor will ask you or them to stay at the medical facility for at least 6 hours. During the 6-hour monitoring, you or the child/adolescent will have:

- Pulse and blood pressure checked every hour
- You or the child/adolescent may be monitored with a continuous ECG during this time
- ECG and blood pressure checked at the end of 6 hours

If, after the 6-hour period, any of the following apply to you or the child/adolescent in your care, you or they may need to be monitored for a longer period until these have resolved:

- You or they have a very slow heart rate
- Your or their heart rate is still decreasing
- Your or their ECG shows certain abnormalities
- You or they have a slow heart rate with concomitant low blood pressure

Similar precautions will also be taken when the child/adolescent's dose is increased from 0.25mg to 0.5mg once daily.

It is important to ensure medication compliance and avoid misuse especially treatment interruption which may result in a requirement to repeat cardiac monitoring. Call the doctor in case of treatment interruption if you or the child/adolescent has stopped Fingolimod for at least:

- 1 day or more during first 2 weeks of treatment
- Or more than 7 days during weeks 3 and 4 of treatment
- Or more than 2 weeks after one month on treatment

as the initial effect on your heart rate may occur again. When Fingolimod therapy is restarted, the doctor may decide to repeat monitoring of heart rate and blood pressure measurements every hour, to run ECGs, and if needed, to monitor you or the child/adolescent overnight.

While you are taking Fingolimod Accord

Infections — Because Fingolimod affects the immune system, those treated with it are more likely to get infections. If the individual taking Fingolimod have any of the following during and up to 2 months after stopping treatment, call their doctor straight away: a headache accompanied by a stiff neck, sensitivity to light, fever, flu-like symptoms, nausea, rash, shingles and or/confusion or seizures (fits) (possible symptoms of meningitis and/or encephalitis, either caused by fungal or viral infection).

If you believe your MS or that of the child/adolescent in your care is getting worse (e.g. weakness or visual changes) or if you notice any new symptoms, talk to their doctor as soon as possible. These may be the symptoms of a rare brain disorder called progressive multifocal leukoencephalopathy (PML), which is caused by an infection.

Cancer – The doctor will assess whether any individuals taking Fingolimod needs to undergo cancer screening (including a Pap test), and if they should receive the human papilloma virus (HPV) vaccine.

Skin cancer— Skin cancers have been reported in MS patients treated with Fingolimod. Inform the 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 in skin tissue (e.g. unusual moles) with a change in colour, shape or size over time.

Blood tests — Some cases of acute liver failure requiring liver transplant and clinically significant liver injury have been reported. A blood test to assess liver function will be required prior to initiation and at months 1,3,6,9 and 12 during Fingolimod therapy and regularly thereafter until 2 months after Fingolimod Accord discontinuation. Inform the doctor if you notice any yellowing of the skin or the whites of the 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.

White blood cell counts will be measured at regular intervals as decided by your doctor to monitor your ability to fight infection.

Pregnancy— You or the child/adolescent in your care should avoid becoming pregnant and should use effective contraception whilst taking Fingolimod, and in the two months after stopping the treatment because there is a risk of harm to the unborn baby. Talk with your or their doctor about reliable methods of birth control that you or they should use.

Immediately report to your or their doctor any (intended or unintended) pregnancy during and for two months following discontinuation of treatment with Fingolimod. Women of child-bearing potential (including female adolescents) should have pregnancy tests repeated at suitable intervals during Fingolimod treatment.

Visual symptoms— Fingolimod may cause swelling at the back of the eye, a condition that is known as macular oedema. Tell the doctor if you or the child/adolescent in your care experiences any changes in vision during and up to 2 months after stopping treatment. If you or the child/adolescent in your care has diabetes or has had inflammation of the eye (uveitis), the doctor will want you or them to undergo additional regular eye examinations, as your or their chances of developing macular oedema are known to be higher.

Seizures — Seizures may occur during treatment. Inform the doctor if you or the child/adolescent in your care, or someone related to them, has a history of epilepsy.

Stopping Fingolimod Accord treatment may result in return of disease activity. The doctor will decide whether and how you or the child/adolescent needs to be monitored after stopping Fingolimod Accord.

Call your or the child/adolescent's doctor in case of treatment interruption. Do not restart Fingolimod after stopping it without seeking advice from your or their doctor.

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