



KEROZ (Fingolimod) Capsules: Patient Caregiver Reminder Card

This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See <https://ade.sfda.gov.sa/>, for how to report side effects or contact PPI Pharmacovigilance department by E-mail: PV@mesned.com and Mobile: +966 551151945

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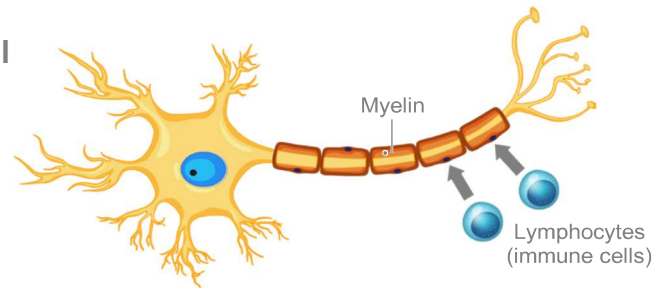
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What is multiple sclerosis (MS)?

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.

Nerve cell



How does KEROZ (Fingolimod) Capsules work?

KEROZ (Fingolimod) Capsules 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 limits nerve damage caused by MS. KEROZ (Fingolimod) Capsules also reduces some of the immune reactions of your body.

Introduction

KEROZ (Fingolimod) Capsules should not be used in patients with specific heart diseases, and is not recommended in patients who are also taking medicines that are known to decrease heart rate.

KEROZ (Fingolimod) Capsules should not be used in women who are pregnant or in women of child-bearing potential 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 KEROZ (Fingolimod) Capsules. 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 KEROZ (Fingolimod) Capsules and up to two months following discontinuation.

Before starting KEROZ (Fingolimod) Capsules treatment

Pregnancy

KEROZ (Fingolimod) Capsules is harm to unborn babies. Women of child-bearing potential (including adolescents) should be informed by their doctor about fingolimod's serious risks to the baby, they must have a negative pregnancy test (checked by a healthcare professional), and must take effective contraception before starting treatment with KEROZ (Fingolimod) Capsules. 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

KEROZ (Fingolimod) Capsules can cause abnormal results in liver function tests. You will need a blood test before starting KEROZ (Fingolimod) Capsules.

Seizures

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

The first time you take KEROZ (Fingolimod) Capsules

Slow heart rate and irregular heartbeat

At the beginning of treatment, KEROZ (Fingolimod) Capsules 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, a sensation of whirling and loss of balance (giddiness), or palpitations or feel uncomfortable after taking the first dose of KEROZ (Fingolimod) Capsules, 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 KEROZ (Fingolimod) Capsules as the first dose monitoring may need to be repeated depending on how many doses you have missed and the duration of KEROZ (Fingolimod) Capsules treatment.

While you are taking KEROZ (Fingolimod) Capsules

Infections

Because KEROZ (Fingolimod) Capsules 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 KEROZ (Fingolimod) Capsules treatment and for 8 weeks after the last dose.

KEROZ (Fingolimod) Capsules can cause a serious rare brain disorder caused by infection and 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 symptoms during KEROZ (Fingolimod) Capsules treatment and for 8 weeks after the last dose.

Skin cancer

Skin cancers have been reported in multiple sclerosis patients treated with KEROZ (Fingolimod) Capsules. 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

KEROZ (Fingolimod) Capsules can cause abnormal results in liver function tests. You will need a blood test at months 1, 3, 6, 9, and 12 during KEROZ (Fingolimod) Capsules therapy and regularly thereafter.

**While you are taking KEROZ (Fingolimod) Capsules
(continued)**

Visual symptoms

KEROZ (Fingolimod) Capsules 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 KEROZ (Fingolimod) Capsules. Talk to your doctor if you are experiencing symptoms.

Stopping KEROZ (Fingolimod) Capsules therapy may result in return of disease activity. Your doctor will decide whether and how you need to be monitored after stopping KEROZ (Fingolimod) Capsules.

Pregnancy

Women of child-bearing potential must have pregnancy tests repeated at suitable intervals during KEROZ (Fingolimod) Capsules treatment.

You should receive regular counselling from a healthcare professional about the serious risks of KEROZ (Fingolimod) Capsules 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 KEROZ (Fingolimod) Capsules, and in the 2 months after you stop taking the treatment because of KEROZ (Fingolimod) Capsules serious risks to the baby.

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

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.

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

SFDA Call Center: 19999

Free Phone: 8002490000

Website: <https://ade.sfda.gov.sa>

email: npc.drug@sfda.gov.sa

Alternatively, you can also report side effects to [Pharmacovigilance department](#) by Email: PV@mesned.com and Mobile:- +966 551151945.

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

Your name: _____

Doctor's name : _____

Doctor's phone number: _____

Indication: _____

Dose: _____

Please fill out information for you and healthcare professionals
involved in your medical care or treatment

