

PATIENT/PARENT/CAREGIVER GUIDE

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

ACH-Fingolimod

(0.5 mg capsules)

Introduction

You have been prescribed ACH-Fingolimod for your multiple sclerosis.

ACH-Fingolimod is not recommended in patients with specific cardiac diseases or those taking medicines at the same time which slow the heart rate. Please tell your doctor about such conditions before being treated with ACH-Fingolimod. If the doctor considers that there is benefit for you to be treated with ACH-Fingolimod, additional care and monitoring, including an overnight stay, may be required.

Please inform your doctors if you or a family member have a history of epilepsy.

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.

Take ACH-Fingolimod for the first time

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

ACH-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 ACH-Fingolimod.

Slow heart rate and irregular heartbeat —

At the beginning of treatment, ACH-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 ACH-Fingolimod, please immediately inform your doctor.

Before you take the first dose, you will have:

- A baseline electrocardiogram (ECG) to assess the condition 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 ACH-Fingolimod for at least 1 day during your first two weeks of treatment, for more than 7 days during your third and fourth weeks, or 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 ACH-Fingolimod therapy, your doctor may decide to monitor you with heart rate and blood pressure measurements every hour, to run ECGs, and if needed to monitor you overnight.

While you are taking ACH-Fingolimod

Infections — While you are taking ACH-Fingolimod, you may get infections more easily because ACH-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 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 — ACH-Fingolimod may cause swelling at the back of the eye, a condition that is known as macular oedema. Tell your doctor about any changes in your vision during treatment and for 2 months after treatment.

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

Blood tests — ACH-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 ACH-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 ACH-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 ACH-Fingolimod. Women of child-bearing age, including female adolescents, should avoid becoming pregnant while taking ACH-Fingolimod or in the 2 months after stopping treatment because there is a risk of harm to the baby. Talk to 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 ACH-Fingolimod.

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.

If you need to see other doctors, remember to tell them that you are taking ACH-Fingolimod.

Please see the “*Patient Information Leaflet*” for more information.