

Olican® (fingolimod) patient reminder card

Important safety information

to remember about
Olican® (fingolimod) treatment for patients, parents and caregivers





Introduction

You have been prescribed Olican® (fingolimod) for your multiple sclerosis. Olican® (fingolimod) is not recommended in patients with specific cardiac problems or those taking medicines that are known to decrease heart rate.

Please tell your doctor about any heart conditions or heart medications you are taking before being treated with Olican® (fingolimod). If the doctor considers that there is benefit for you to be treated with fingolimod, additional care and monitoring, including overnight stay after taking the first dose, may be required.

Olican® (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.

Reporting of side effects

If you experience any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report any suspected side effects directly to:

- **The National Pharmacovigilance Centre (NPC)**

SFDA Call Center: 19999

E-mail: npc.drug@sfd.gov.sa

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

- **Pharmacovigilance department, Pharmascience Inc.:**

Local QPPV

Tel: +966 55 779 9082

Email: aalimousa@balsam-cr.com

Deputy Local QPPV

Tel: +966 55 426 2128

Email: sbinhuwaimel@balsam-cr.com

By reporting side effects, you can help provide more information on the safety of this medicine.





Taking Fingolimod for the First time

Your doctor will ask you to stay at the clinic/hospital for 1 or more hours after taking the first dose so that you can be monitored and appropriate measures can be taken if side effects occur.

Your ability to drive an automobile or operate dangerous equipment may be impaired during the first day of treatment.

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, vertigo, nausea or palpitations, or feel uncomfortable after taking the first dose of fingolimod, please inform your doctor immediately.

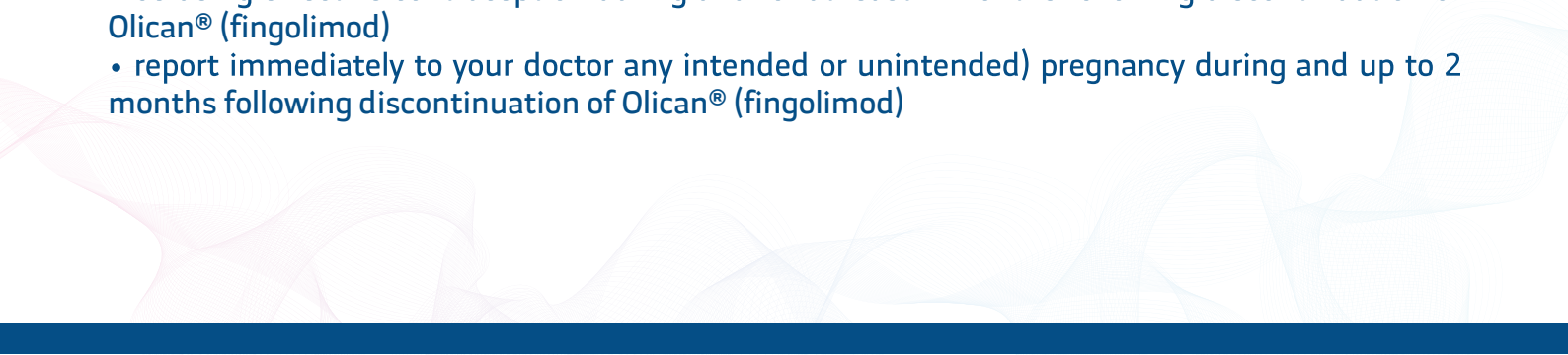
Before you take the first dose, you will have:

- A baseline electrocardiogram (ECG) to assess the action of your heart
- A blood pressure measurement
- Possibly a pregnancy test
- One or more blood tests to check your immune system and liver function
- Eye examination
- Possibly lung function tests

Before starting Olican[®] (fingolimod)

Pregnancy

Olican[®] (fingolimod) is teratogenic (causes defects to unborn babies). If you are a woman of child-bearing potential (including adolescent), you should

- be informed before treatment initiation and regularly thereafter by your doctor about Olican[®] (fingolimod) serious risks to the foetus and about the contraindication in pregnant women of childbearing potential not using effective contraception
 - have a negative pregnancy test before starting Olican[®] (fingolimod)
 - be using effective contraception during and for at least 2 months following discontinuation of Olican[®] (fingolimod)
 - report immediately to your doctor any intended or unintended pregnancy during and up to 2 months following discontinuation of Olican[®] (fingolimod)
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Liver function

Olican® (fingolimod) can cause abnormal results in liver function tests. You will need a blood test before starting Olican® (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.

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. If you have stopped Olican® (fingolimod) for at least 1 day during your first 2 weeks of treatment, if you have stopped Olican® (fingolimod) for more than 7 days during weeks 3 and 4 of treatment, or if you have stopped Olican® (fingolimod) 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 Olican® (fingolimod) therapy, your doctor may decide to monitor your heart rate and blood pressure measurements every hour, to perform ECGs, and, if needed, to monitor you overnight.

While you are taking Olican® (Fingolimod)

• Slow heart rate and irregular heart beat

Olican® (fingolimod) causes the heart rate to slow down especially during the first month of treatment. If you experience any dizziness, palpitations (rapid or irregular heart rate), fainting or seizures see medical attention.

• Infections

While you are taking Olican® (fingolimod) and up to 2 months after stopping treatment you may get infections more easily. If you think you have an infection, have a fever, feel like you have the flu, or have a headache accompanied by a stiff neck, sensitivity to light, nausea, and/or confusion (these may be caused by a serious fungal infection and may be symptoms of meningitis) 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

Olican® (fingolimod) may cause swelling at the back of the eye, a condition that is known as macular edema. Tell your doctor immediately about any changes in your vision during and up to 2 months after treatment.

• Blood tests

Olican® (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 fingolimod therapy and regularly thereafter.

If your test results indicate a problem with your liver you may have to interrupt treatment with Olican® (fingolimod). Do not restart Olican® (fingolimod) after stopping it for more than 2 weeks without seeking advice from your doctor.

A completed blood count (CBC) will also be required before treatment initiation.

• Skin growth

A type of skin cancer called basal cell carcinoma (BCC) has been reported in multiple sclerosis patients treated with Olican® (fingolimod). Talk to your doctor if you notice any skin nodules (e.g. shiny pearly nodules), patches or open sores that do not heal within weeks (these may be signs of BCC). Other skin cancers have also been reported in multiple sclerosis patients treated with Olican® (fingolimod). 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.

• Pregnancy

If you are of child-bearing potential you need to have a negative pregnancy test before taking Olican® (fingolimod) and at suitable intervals during treatment. You should avoid becoming pregnant while taking Olican® (fingolimod) and in the 2 months after you stop taking the treatment because there is a risk of harm to the baby.

Talk with your doctor about reliable methods of birth control that you should use during treatment and for 2 months after you stop treatment.

Immediately report any (intended or unintended) pregnancy to your doctor during treatment and for 2 months following discontinuation of treatment with Olican® (fingolimod).

All pregnancies should be reported by calling NPC.





If you need to see other doctors, remember to tell them that you are taking Olican® (fingolimod).

Your ability to drive an automobile or operate dangerous equipment may be impaired during the first day of treatment.

Do not restart Olican® (fingolimod) after stopping it for more than 2 weeks without seeking advice from your doctor.

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

For further information, please consult the Patient Information Leaflet for Olican® (fingolimod).

