

FINGOLIMOD

PATIENT/PARENT/CAREGIVER'S GUIDE Fingolimod Zentiva (fingolimod)

Important things to know about Fingolimod Zentiva (fingolimod) treatment.

This guide is designed to offer important information that you need to know if you or a person in your care are starting treatment with fingolimod. Please speak to your doctor if you have any further questions about your treatment or the information in this guide.

WHAT IS MULTIPLE SCLEROSIS (MS)?

MS is a long-term condition that affects the central nervous system (CNS), which is made up of the brain and spinal cord.

In MS, the immune system attacks the protective sheath (called myelin) around the nerves in the CNS. This stops the nerves from working properly.

Relapsing-remitting MS (RMS) 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 WORK ?

It is not fully understood how fingolimod therapy works in MS.

Immune cells (lymphocytes) that interact with fingolimod become trapped in the lymph nodes, which stops them from reaching the brain and spinal cord, **preventing** them causing inflammation.

This limits the nerve damage caused by MS.

Fingolimod also reduces some of the immune reactions of your body.

PRECAUTIONS AND CONTRAINDICATIONS

Please note:

Please read the Patient Information Leaflet thoroughly before starting treatment with fingolimod.

Contact your doctor immediately if you experience any adverse reactions during treatment with fingolimod or in case of pregnancy.

Please tell any doctor you see that you are taking fingolimod.

Cardiac diseases and medication:

Inform your doctor if you have **underlying cardiac conditions**.

Inform your doctor if you are taking medicines that are known to **decrease heart rate**.

Opportunistic infections risk:

Your doctor will monitor blood lymphocyte counts prior to starting treatment with fingolimod.

Liver function:

Inform your doctor if you have liver problems.

Pregnancy:

Fingolimod must **not be used** in women who are pregnant or women who could become pregnant, who are not using effective contraception.

If you are a woman who could become pregnant, you should be informed by your doctor about the serious risks to the fetus caused by fingolimod.

If you are a woman of child-bearing potential, you or your caregiver will be provided with a **Pregnancy-Specific Patient Reminder Card**.

BEFORE STARTING FINGOLIMOD TREATMENT

Screenings:

Before taking the first dose, you will have:

- A baseline electrocardiogram (ECG) to assess the action of your heart
- A blood pressure measurement.
- Liver function tests will be taken prior to treatment initiation as fingolimod can cause abnormal results in liver function tests and liver injury.
- Blood lymphocyte counts will be performed prior to starting treatment with fingolimod.

Your doctor may arrange an **eye assessment** before starting fingolimod as well as a follow-up eye assessment 3-4 months after starting treatment.

For women of child-bearing potential, a **pregnancy test** must be carried out and **negative results** verified by your doctor before starting treatment.

Your doctor will arrange magnetic resonance imaging (**MRI**) **scans** before you start treatment and during treatment to monitor the risk of **progressive multifocal leukoencephalopathy (PML)**. PML is a rare brain disorder caused by an infection that may lead to severe disability or death.

TAKING FINGOLIMOD FOR THE FIRST TIME

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 your blood pressure. **Immediately inform your doctor** if you experience any symptoms such as dizziness, nausea, vertigo, or palpitations which may be signs of a low heart rate, or if you feel uncomfortable after taking your first dose of fingolimod.

6-hour monitoring:

Your doctor will ask you to stay at the surgery or clinic 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.

During the 6-hour monitoring, you will have:

- Your pulse and blood pressure checked every hour
 - You may be monitored with continuous ECG during this time
- An ECG at the end of 6 hours

WHILE TAKING FINGOLIMOD

Treatment Interruption:

Call your doctor in case of treatment interruption:

If you have stopped fingolimod for 1 day or more during the first 2 weeks of treatment, or for more than 7 days during weeks 3 and 4 of treatment, or if you have stopped fingolimod for more than 2 weeks after you have been on treatment for at least 1 month, the initial effect on your heart rate may occur again. When you restart your 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.

Visual symptoms:

Fingolimod may cause swelling at the back of the eye, a condition that is known as macular edema. Tell your doctor if you experience any changes in your vision during and up to 2 months after stopping treatment.

Your doctor may arrange an eye assessment before starting fingolimod and as required during treatment. A follow-up eye assessment may be done 3-4 months after starting treatment.

Infections

Because fingolimod affects the immune system, people taking fingolimod are more likely to get infections. If you think you have any of the following, during and up to 2 months after stopping treatment, **call your 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).

Blood lymphocyte counts

Your doctor will monitor blood lymphocyte counts during treatment with fingolimod. Treatment with fingolimod may be interrupted if blood lymphocyte count is too low.

Worsening of MS symptoms:

Inform your doctor straight away if you believe your MS is getting worse or if you notice any new symptoms, for example:

- changes in mood or behaviour,
- new or worsening weakness on one side of the body,
- changes in vision,
- confusion,
- memory lapses,
- speech and communication difficulties.

These may be the symptoms of **progressive multifocal leukoencephalopathy** (PML is a rare brain disorder caused by an infection that may lead to severe disability or death) or of an inflammatory reaction (known as **immune reconstitution inflammatory syndrome** or IRIS) that can occur in patients with PML as fingolimod is removed from their body after they stop taking it. Your doctor will arrange MRI scans during treatment to monitor the risk of PML.

Speak with your partner or caregivers and inform them about your treatment. Symptoms might arise that you might not become aware of by yourself.

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

Some cases of acute liver failure requiring liver transplant and clinically significant liver injury have been reported. After starting fingolimod, you will need a blood test at months 1, 3, 6, 9, and 12, and regularly thereafter while on treatment until 2 months after fingolimod discontinuation. **Inform your doctor immediately if you notice:**

- yellowing of your skin or the whites of your eyes,
- abnormally dark urine,
- pain on the right side of the stomach area,
- tiredness,
- feeling less hungry than usual,

- unexplained nausea and vomiting.

These can be signs of liver injury.

Pregnancy:

Fingolimod must not be used in women who could become pregnant and are not using effective contraception, or who are pregnant.

Women of child-bearing potential must:

- have pregnancy tests repeated at suitable intervals during fingolimod treatment,
- receive regular counselling from a healthcare professional facilitated by the Pregnancy-Specific Patient Reminder Card about the serious risks of fingolimod to the fetus,
- use effective contraception whilst taking fingolimod, and in the 2 months after you stop taking the treatment because of the serious risks to the fetus caused by fingolimod,
- immediately report to your doctor any (intended or unintended) pregnancy during treatment and for 2 months following discontinuation of treatment with fingolimod.

Paediatric patients

Please note: All adult precautions and contraindications apply also for paediatric patients.

In addition:

Screenings:

For paediatric patients, in addition to the screenings listed above, their doctor will also assess:

- Height and weight
- Puberty status
- Vaccination status

6-hour monitoring:

For paediatric patients, 6-hour monitoring (or similar precautions) will also be taken when the dose is increased from 0.25 mg to 0.5 mg once daily.

Depression and anxiety during treatment:

Both depression and anxiety have been reported in paediatric patients treated with fingolimod. If the child/adolescent in your care is experiencing symptoms, talk to their doctor.

REPORTING OF SIDE EFFECTS

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in the information leaflet that comes in the pack. Suspected adverse reactions may also be reported to the Kosovo Agency for Medicinal Products and Medical Devices (KAMPM).

Electronically:

info@akkpm-rks.gov

By mail:

Kosovo Agency for Medicinal Products and Medical Devices (KAMPM)

Hospital Circle, n.n. (UCCK)

10000 Prishtina, Kosovo

By fax:

+383 38 512 243

You may also report suspected adverse reactions to the Marketing Authorisation Holder (MAH) in Kosovo.

Contact details of the local qualified person responsible for pharmacovigilance on behalf of the Marketing Authorisation Holder:

Tringa Rraci, MPharm

Local Person Responsible for Pharmacovigilance (LPPV)

MAH Zentiva Pharma GmbH

Pharmakos LLC

Tel: +383 49 621 621

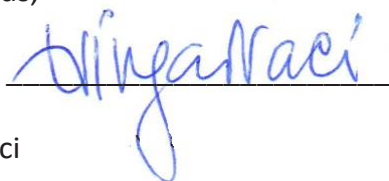
E-mail: pharmacovigilance@pharmakos.biz

PV-Kosovo@zentiva.com

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

Kind regards,

Signature:



Tringa Rraci

- Reference / Link / QR code to local SmPC or package leaflet with a reminder to carefully read the SmPC or package leaflet (as appropriate, not to be version-vulnerable; usually local registry managed by competent authority or other acknowledged body)
- Reference / Link / QR code to electronic educational material (as appropriate, not specific to particular document, not to be version-vulnerable; usually competent authority or Zentiva web-site)
- Statement that the aRMM material fulfills the conditions of the marketing authorisation and has been approved by the competent authority, including the version number and the date of its approval in the format „month“ „year“ on the first and/or last page.
- Other local specific requirements, e.g. local specific requirements on specific aRMM/educational/safety advice tool **symbol/text/fonts/colours/etc.** to be respected.
- ICSR Reporting Instructions (to be completed locally based on local requirements)
- Local Contact

Sources of Global document:

- SmPC
FINGOLIMOD HYDROCHLORIDE_0.5 mg_hard capsule_EN_PT-H-2285-001_EPAR_250115
- RMP
Fingolimod_RMP_08_12_2025_V2.1_PT2285
- Educational material of reference product Gilenya
 - IE [link](#) (date approved by the HPRA: July 2025)