FINGOLIMOD

PREGNANCY-SPECIFIC PATIENT REMINDER CARD
Fingolimod Zentiva (fingolimod)

This booklet is for patients who have already been prescribed Fingolimod Zentiva and it does not replace the Patient Information Leaflet (PIL) that comes with your medication, or advice from your doctor or nurse. Always read the PIL before starting your treatment and use Fingolimod Zentiva exactly as your doctor or nurse has described.

BEFORE STARTING FINGOLIMOD TREATMENT

- **Fingolimod is contraindicated in pregnant women and women of child-bearing potential (including adolescents) not using effective contraception.**
- At treatment start and then regularly, your doctor will inform you about the teratogenic risk (causes defects to unborn babies) and required actions to minimise this risk.
- A pregnancy test must be conducted and the negative result verified by a doctor before starting treatment.
- Your doctor will inform you about the need for effective contraception while on treatment and for 2 months after discontinuation. Talk to your doctor about the most effective contraception options available to you.
- Please read the fingolimod Patient Guide provided by your doctor.

WHILE YOU ARE TAKING FINGOLIMOD

- While on treatment women must not become pregnant.
- Patients must use effective contraception while taking fingolimod.
- Women must not become pregnant during treatment and for 2 months after discontinuing treatment.
- Pregnancy tests must be repeated at suitable intervals.
- Your doctor will provide regular counselling about fingolimod’s serious risks to foetus.
- If you become pregnant or if you want to become pregnant tell your doctor straight away because fingolimod treatment must be discontinued.
- In the event of a pregnancy your doctor will provide counselling.
- Your doctor will give you medical advice regarding the harmful effects of fingolimod to the foetus and will provide an evaluation of the potential outcome.

AFTER STOPPING FINGOLIMOD TREATMENT

- Inform your doctor immediately if you believe your MS is getting worse (e.g. weakness or visual changes) or if you notice any new symptoms after stopping treatment with fingolimod due to pregnancy.
- Effective contraception is needed for 2 months after stopping fingolimod treatment because of the length of time it takes for fingolimod to leave the body.

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.

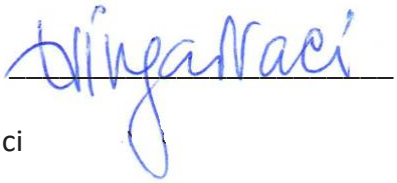
Contact details of the local qualified person responsible for pharmacovigilance on behalf of the Marketing Authorisation Holder:

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
  UK link (approved by MHRA 03-April-2024)