



After stopping GILENYA® 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 GILENYA® due to pregnancy.
- Effective contraception is needed for 2 months after stopping GILENYA® treatment because of the length of time it takes for GILENYA® to leave the body.



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

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GILENYA® (fingolimod)

Pregnancy-Specific Patient Reminder Card

If you get any side effects, talk to your doctor, pharmacist or nurse. By reporting side effects, you can help provide more information on the safety of this medicine. You can report side effects directly via HPRA Pharmacovigilance, website: www.hpra.ie. Side effects could also be reported to Novartis preferably via www.report.novartis.com, or by email to drugsafety.dublin@novartis.com or by calling 01 2080 612.

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Before starting GILENYA® treatment



- **GILENYA® (fingolimod) must not be taken if you are pregnant, trying to become pregnant or a woman of child-bearing potential (including female adolescent) not using effective contraception.**



- GILENYA® can harm an unborn baby (the medicine is said to be 'teratogenic'). Before you start treatment with GILENYA®, your doctor will inform you about the risks to an unborn baby and explain what you should do to avoid becoming pregnant while you are taking GILENYA®.

- Your doctor will ask you to take a pregnancy test to ensure that you are not pregnant before you start treatment with GILENYA®.



- Your doctor will explain the need for effective contraception while on treatment and for 2 months after stopping treatment. Talk to your doctor about the most effective contraception options available to you.

- Please read the GILENYA® Patient/Parent/Caregiver Guide provided by your doctor.

While you are taking GILENYA®



- You must not become pregnant while taking GILENYA® and for 2 months after stopping treatment.

- You must use effective contraception while taking GILENYA® and for 2 months after you stop taking it, to avoid becoming pregnant.

- Your doctor will ask you to repeat pregnancy tests at suitable intervals during treatment.



- Your doctor will provide you with regular counselling about GILENYA®'s serious risk to an unborn baby.

- Tell your doctor straight away if you become pregnant or if you want to become pregnant because your doctor will stop your treatment with GILENYA®.

While you are taking GILENYA®



- In the event of a pregnancy, GILENYA® must be discontinued. Your doctor will provide counselling on the serious risk to the unborn baby and ultrasonography examinations should be performed.



- Your doctor will encourage you to enroll in the GILENYA® Pregnancy Registry: <https://www.gilenyapregnancyregistry.com/>

- The purpose of this registry is to monitor the outcomes of pregnancy in women exposed to GILENYA® during pregnancy.