# Gilenya® (fingolimod) ▼: Pregnancy-Specific Patient Reminder Card

**▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.**

April 2021

# Before starting Gilenya treatment

**Gilenya (fingolimod) is contraindicated in pregnant women and women of child-bearing potential (including female adolescents) not using effective contraception**.

At treatment start and then regularly, your doctor will inform you about the teratogenic risk and required actions to minimize 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 Gilenya Patient Guide Leaflet provided by your doctor.

# While you are taking Gilenya

While on treatment women must not become pregnant.

Patients must use effective contraception while taking Gilenya.

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 Gilenya's serious risks to the fetus.

If you become pregnant or if you want to become pregnant please discuss this with your doctor because Gilenya treatment must be discontinued.

# While you are taking Gilenya

In the event of a pregnancy your doctor will provide counselling.

Your doctor will give you medical advice regarding the harmful effects of Gilenya to the fetus and will provide an evaluation of the potential outcome.

An ultrasonography examination should be performed, and Gilenya treatment will be discontinued

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.

# 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.

Suspected Adverse Drug Reactions (side effects) and medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at http://www.medicinesauthority.gov.mt/adrportal and sent by post or email to;

**P:** Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann. SGN 3000.

**E:** postlicensing.medicinesauthority@gov.mt.

Healthcare Professionals may also report any adverse events associated with the use of **Gilenya** to Novartis Pharma Services Inc., Representative Office, Malta, by phone on +356 21222872, online on www.report.novartis.com or by e-mail at drug_safety.malta@novartis.com.

Marketing Authorization Holder: Novartis Europharm Limited, Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland.
Local Representative: Novartis Pharma Services Inc., Representative Office Malta.
Tel No.: +356 21222872

**For electronic copies of this Educational Material, please refer to the Malta Medicines Authority website -** http://www.medicinesauthority.gov.mt/rmm **- and download the required material with the latest date.**



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