Gilenya
patient
information

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

▼ This medicinal product is subject to additional monitoring.
For more information, please see back page.

Approved by MHRA 03/2020

Before starting Gilenya treatment

Gilenya (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 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 foetus.

If you become pregnant or if you want to become pregnant please discuss this with your doctor because Gilenya 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 Gilenya to the foetus and will provide an evaluation of the potential outcome.

While you are taking Gilenya (continued)

Your doctor will encourage you to enrol 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.

Reporting of side effects

If you get side effects with any medication you are taking, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the information leaflet that comes in the pack.

You can also report the side effect. It is easiest and quickest to report side effects online via the Yellow Card website https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store.

Alternatively, prepaid Yellow Cards for reporting are available by writing to FREEPOST YELLOW CARD (no other address details necessary), by emailing yellowcard@mhra.gov.uk, at the back of the British National Formulary (BNF), by telephoning the Commission on Human Medicines (CHM) free phone line: 0800 731 6789, or by downloading and printing a form from the Yellow Card section of the MHRA website.

By reporting side effects you can help provide more information on the safety of your medication.

All pregnancies should be reported to Novartis Patient Safety via uk.patientsafety@novartis.com or 0845 601 1387.

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▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See www.mhra.gov.uk/yellowcard for how to report side effects.

For further information please contact Novartis Pharmaceuticals UK Medical Information Department: 01276 698370 or medinfo.uk@novartis.com

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