Gilenya patient information

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

This booklet is for patients who have already been prescribed Gilenya 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 Gilenya exactly as your doctor or nurse has described.

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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 tell your doctor straight away 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

Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme, via the Yellow Card website https://yellowcard.mhra.gov.uk, the free Yellow Card app available in Apple App Store or Google Play Store, and also some clinical IT systems for healthcare professionals. Alternatively you can call 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

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

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