### 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.

#### Further information and questions



For more information about MS please see www.ms-society.ie.



Please read the package leaflet for more details about the appropriate use of Gilenya.



 $\mid$  If you have any questions about the information in this guide, please contact your doctor.

For information on medication exposure during pregnancy, please go to the UK Teratogenic Information Service on:

https://www.medicinesinpregnancy.org/leaflets-a-z/fingolimod/ Accessed March 2025

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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 to HPRA Pharmacovigilance at www.hpra.ie. Side effects can also be reported to Novartis preferably at www.novartis.com/report, by emailing drugsafety.dublin@novartis.com or by calling (01) 2080 612

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#### **Contraindication**

IF USED DURING PREGNANCY,
GILENYA CAN HARM YOUR UNBORN BABY.

Gilenya (fingolimod) must not be used in pregnant women and women of child-bearing potential not using effective contraception.

It is important that you use effective contraception while taking GILENYA and for 2 months after you stop taking it to avoid becoming pregnant. Your doctor will provide counselling regarding effective contraception.



## **Beginning Gilenya treatment**



Gilenya is teratogenic (an agent which causes an abnormality following fetal exposure during pregnancy, resulting in birth defects or malformations).



At the start of your treatment and then regularly during treatment, your doctor will inform you about the teratogenic risk 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



Women must not become pregnant during Gilenya treatment and for 2 months after discontinuing treatment.



Must use effective contraception while taking Gilenya and for 2 months after discontinuing treatment.



Pregnancy tests must be repeated at suitable intervals.



Your doctor will provide counselling regularly regarding the risks of Gilenya harming an unborn baby if you become pregnant and required actions to minimise the risk.



If you become pregnant or if you want to become pregnant, Gilenya treatment **must be** discontinued.



Inform your doctor **immediately** if you think you are pregnant. Your doctor will provide counselling in the event of pregnancy and an evaluation of the potential outcome of any pregnancy.