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

NOVARTIS | Reimagining Medicine

GILENYA/PC/RMP Vs.20.2/FEB 2025/FA-11417854 02 JUNE 2025

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 harm or abnormalities in the development of the embryo or fetus following 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 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

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

Women 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 minimize 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.

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 and Gilenya, please see http://www.medicinesauthority.gov.mt/rmm

Please read the package insert for more detailed information about the appropriate use of Gilenya.
For more detailed guidance on GILENYA please refer to the Summary of Product Characteristics (SmPC) available at https://www.ema.europa.eu/en/medicines/human/EPAR/gilenya

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

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.

This educational material is a part of the conditions of the Marketing Authorization.

Gilenya is a registered trademark of Novartis Pharma AG.