

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

This booklet is for patients who have already been prescribed fingolimod, and it does not replace the Patient Information Leaflet (PIL) that comes with your medication, or advice from your doctor. Always carry and read the PIL before starting your treatment and use fingolimod exactly as your doctor has described.

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

Do not use fingolimod during pregnancy, if you are trying to become pregnant, or if you are a woman who could become pregnant (including adolescents) and you are not using effective contraception.

At the start of treatment and then regularly during treatment, 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.

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

Please read the fingolimod Patient Guide provided by your doctor.

Important steps to minimising the risk with fingolimod

If you would like to become pregnant, you should discuss your treatment with your doctor who will explain your treatment options including discontinuing fingolimod. Your doctor will also monitor closely your disease activity.

You should not just stop fingolimod because you are planning a pregnancy. If you become pregnant unexpectedly, your doctor will provide counselling regarding the risk of fingolimod harming an unborn baby and the required actions to minimise the risks.

If you become pregnant, tell your doctor straight away to discuss your disease management including discontinuation of fingolimod.

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 fingolimod due to pregnancy.

Your doctor will also explain the risk of rebound activity if fingolimod is discontinued and advise you on your treatment options.

Reporting 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.

Please report side effects to the MHRA through the Yellow Card scheme, via the Yellow Card website www.mhra.gov.uk/yellowcard, the free Yellow Card app available in Apple App Store or Google Play Store. 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.