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.

Before starting Fingolimod treatment

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 treatment start 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.

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 Fingolimod Patient Guide Leaflet provided by your doctor.

Important steps to minimizing 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 or if you want to become pregnant, please discuss this with your doctor because Fingolimod treatment must be discontinued.

Inform your doctor immediatelyif 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 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 report the side effects either to the Medicines Authority or to Tillomed.

Suspected Adverse Drug Reactions (side effects) or 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 Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 E: postlicensing.medicinesauthority@gov.mt

All pregnancies should be reported by:

- **Telephone/Email:** Call the Tillomed Pharmacovigilance department at +44 (0)1480 402 400 or email at PVUK@tillomed.com.

For further information please contact Tillomed Medical Information department: +44 (0)1480 402 400 or email at: medical.information@tillomed.com

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