Fingolimod

Pregnancy-Specific Patient Reminder Card

Before starting Fingolimod treatment

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 Fingolimod Patient Guide Leaflet provided by your doctor.

While you are taking Fingolimod

While on treatment women must not become pregnant.

Patients must use effective contraception while taking Fingolimod.

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 Fingolimod’s serious risks to the foetus.

If you become pregnant or if you want to become pregnant, please discuss this with your doctor because Fingolimod 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 Fingolimod to the foetus and will provide an evaluation of the potential outcome.

After stopping Fingolimod 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 Fingolimod due to pregnancy.

Effective contraception is needed for 2 months after stopping Fingolimod treatment because of the length of time it takes for Fingolimod to leave the body.

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.

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