

Fingolimod Tillomed (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 Tillomed by emailing medical.information@tillomed.com or by calling +44 (0)800 9706115.

IF USED DURING PREGNANCY, FINGOLIMOD CAN HARM YOUR UNBORN BABY. Do not take fingolimod if you are pregnant or you are a woman of childbearing potential not using effective contraception

Educational materials fulfil the conditions of the marketing authorisation and have been approved by the Health Products Regulatory Authority (HPRA).

Beginning fingolimod treatment

- Fingolimod 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 Fingolimod Patient Guide Leaflet provided by your doctor.

While you are taking fingolimod

- Women must not become pregnant during fingolimod treatment and for 2 months after discontinuing treatment.
- Must use effective contraception while taking fingolimod 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 fingolimod 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, fingolimod 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 fingolimod treatment

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.

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.