

Fingolimod SUN

Pregnancy-specific patient reminder card

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

- FINGOLIMOD is contraindicated during pregnancy and in women of childbearing potential not using effective contraception;
- Doctors will provide counselling before treatment initiation and regularly thereafter regarding the teratogenic risk of FINGOLIMOD and required actions to minimise this risk.
- Patients must use effective contraception while taking FINGOLIMOD;
- A pregnancy test must be carried out and negative results verified by the doctor before starting treatment. It must be repeated at suitable intervals;
- Patients will be informed by their doctor of the need for effective contraception while on treatment and for 2 months after discontinuation;
- Doctors will provide counselling in the event of pregnancy and evaluation of the outcome of any pregnancy;
- While on treatment, women must not become pregnant. If a woman becomes pregnant or wants to become pregnant, FINGOLIMOD must be discontinued;
- Patients should inform their doctor straight away if there is worsening of multiple sclerosis after stopping treatment with FINGOLIMOD;

This medicine is under additional monitoring; consequently patients are encouraged to report side effects. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the CMI. You can also report side effects directly via <http://www.tga.gov.au/reporting-problems>. By reporting side effects you can help provide more information on the safety of this medicine.