

Fingolimod SUN

Pregnancy-specific patient reminder card

This reminder card does not replace the product information (PI)

Please refer to the Patient/Caregiver Guide and the Consumer Medicine Information (CMI) for comprehensive information on the safe use of this medicine, including important guidance regarding pregnancy.

▼ 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.
- **IF USED DURING PREGNANCY, FINGOLIMOD CAN HARM YOUR UNBORN BABY.**
- 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.
- If patient would like to become pregnant, patient should discuss treatment with the doctor who will explain the treatment options including discontinuing FINGOLIMOD. Doctor will also monitor closely the disease activity.
- Patient should not just stop FINGOLIMOD because she will be planning a pregnancy. If patient become pregnant unexpectedly, the doctor will provide counselling regarding the risk of FINGOLIMOD harming an unborn baby and the required actions to minimise the risks.
- Patients should inform their doctor straight away if there is worsening of multiple sclerosis or noticed any new symptoms after stopping treatment with FINGOLIMOD.
- Doctor will also explain the risk of rebound activity if FINGOLIMOD is discontinued and advise patient on treatment options.

Fingolimod SUN things to remember about

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."