

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.

If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the Patient Information Leaflet. You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

You can also report side effects directly to Mylan IRE Healthcare Limited using the following contact details: pv.ireland@viatris.com

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Fingolimod Mylan 0.5 mg hard capsules

PREGNANCY-SPECIFIC

Patient Reminder Card

Important information on pregnancy prevention and contraception

Before starting fingolimod treatment

- Fingolimod can seriously harm an unborn baby. You must not take fingolimod if you are pregnant, trying to become pregnant or a woman of childbearing potential (including adolescent) not using effective contraception.
- Your doctor will inform you about the **serious** risks of fingolimod to an unborn baby and **will explain what you need to do to avoid becoming pregnant whilst taking fingolimod.**
- **Your doctor will ask you to perform a pregnancy test to make sure that you are not pregnant** before starting treatment.
- **Talk to your doctor about effective contraception.**
- Your doctor will inform you about the need for effective contraception while on treatment and for 2 months after discontinuation.
- Please read the Patient/Parent/Caregiver's Guide provided by your doctor.

While you are taking fingolimod

- **You must use** effective contraception **without interruption** while taking fingolimod **and for up to 2 months after stopping treatment to avoid becoming pregnant.**
- Pregnancy tests must be repeated at suitable intervals.
- Your doctor will provide you with regular counselling about fingolimod's serious risk to an **unborn baby.**
- If you become pregnant **or think you may be pregnant contact your doctor straight away.**
- **If you are thinking about having a baby,** talk to your doctor so that they can change your treatment. Fingolimod will need to be stopped 2 months before planning a pregnancy.

Actions to be taken in the event of a pregnancy

- In the event of a pregnancy, fingolimod must be stopped. 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.