

Date of preparation: November 2024
Date of HPRA approval: January 2025
2025/ADV/FIN/010C



Please see the "Patient Information Leaflet" for more information.

If you get any side effects talk to your doctor, pharmacist, or nurse.
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.
Side effects may also be reported to Clonmel Healthcare e-mail:
medicalinformation@clonmel-health.ie or Tel: (052) 617 7777.

Fingolimod Clonmel (fingolimod)

Pregnancy-Specific Patient Reminder Card

This Educational material was developed by Clonmel Healthcare Ltd. to fulfil the conditions of the marketing authorisation and has been approved by the HPRA.

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Before starting fingolimod treatment

Fingolimod must not be taken if you are pregnant, trying to become pregnant or a woman of child-bearing potential (including female adolescent) not using effective contraception.

- Fingolimod can harm an unborn baby (the medicine is said to be 'teratogenic'). Before you start treatment with fingolimod, your doctor will inform you about the risks to an unborn baby and explain what you should do to avoid becoming pregnant while you are taking fingolimod.
- Your doctor will ask you to take a pregnancy test to ensure that you are not pregnant before you start treatment with fingolimod.
- Your doctor will explain the need for effective contraception while on treatment and for 2 months after stopping treatment. Talk to your doctor about the most effective contraception options available to you.
- Please read the Patient/Parent/Caregiver guide provided by your doctor.

While you are taking fingolimod

- You must not become pregnant while taking fingolimod and for 2 months after stopping treatment.
- You must use effective contraception while taking fingolimod and for 2 months after you stop taking it, to avoid becoming pregnant.
- Your doctor will ask you to repeat pregnancy tests at suitable intervals during treatment.
- Your doctor will provide you with regular counselling about fingolimod's serious risk to an unborn baby.
- Tell your doctor straight away if you become pregnant or if you want to become pregnant because your doctor will stop your treatment with fingolimod.

While you are taking fingolimod

- In the event of a pregnancy, fingolimod must be discontinued. Your doctor will provide counselling on the serious risk to the unborn baby and ultrasonography examinations should be performed.

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.