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.

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.

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

Date of Preparation: September 2022 **Date of HPRA Approval:** September 2022

Fingolimod Accord

(fingolimod)

PREGNANCY-SPECIFIC

Patient Reminder Card

Date of HPRA Approval: September 2022

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BBBB3005

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 fingolimod patient guide entitled "Fingolimod Accord 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.

While you are taking fingolimod

- 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.
- 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.