

This educational material contains important safety information about Mylan-Fingolimod (fingolimod) and advice on risk minimization.

This booklet was developed by MAH.

Before starting Mylan-Fingolimod treatment

Mylan-Fingolimod (fingolimod) is contraindicated in pregnant women and women of child-bearing potential (including adolescents) not using effective contraception.

At the start of treatment and regularly thereafter, your doctor will inform you about the teratogenic risk (causes defects to unborn babies) of taking Mylan-Fingolimod and required actions to minimize this risk.

A pregnancy test must be conducted, and the negative result verified by a doctor before starting treatment.

Your doctor will inform you about the need for effective contraception while on treatment and for 2 months after discontinuation. Talk to your doctor about the most effective contraception options available to you.

Please read the Mylan-Fingolimod Patient/Parent/Caregiver Guide provided by your doctor.

While you are taking Mylan-Fingolimod

While on treatment women must not become pregnant. You must use effective contraception while taking Mylan-Fingolimod.

Women must not become pregnant during treatment and for 2 months after discontinuing treatment.

Pregnancy tests must be repeated at suitable intervals.

Your doctor will provide regular counseling about Mylan-Fingolimod's serious risks to the fetus.

If you become pregnant or if you want to become pregnant, please discuss this with your doctor because Mylan-Fingolimod treatment must be discontinued.

In the event of a pregnancy, your doctor will provide counseling.

Your doctor will give you medical advice regarding the harmful effects of Mylan-Fingolimod to the fetus and will provide an evaluation of the potential outcome.

Your doctor will encourage you to enroll in the Mylan-Fingolimod Pregnancy Registry: <https://www.mylanfpr.ca/en-ca>.

The purpose of this registry is to monitor the outcomes of pregnancy in women exposed to Mylan-Fingolimod during pregnancy.

After stopping Mylan-Fingolimod treatment

Inform your doctor immediately if you believe your multiple sclerosis (MS) is getting worse (e.g. weakness or visual changes) or if you notice any new symptoms after stopping treatment with Mylan-Fingolimod due to pregnancy.

Effective contraception is needed for 2 months after stopping Mylan-Fingolimod treatment because of the length of time it takes for Mylan-Fingolimod to leave the body.

Reporting of side effects

If you get side effects with any medication you are taking, talk to your health care professional. This includes any possible side effects not listed in the information leaflet that comes in the pack.

You can also report the side effect. It is easiest and quickest to report side effects online by: Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>);

or

By calling toll-free at 1-866-234-2345.

By reporting side effects, you can help provide more information on the safety of your medication.

All pregnancies should be reported to Mylan-Fingolimod Pregnancy Registry. You can enroll in this registry by calling: 1-888-246-5830 or by fax at 1-833-677-0484 or visiting <https://www.mylanfpr.ca/en-ca>.