

#### Reporting Adverse Events:

Adverse events can be reported to the Ministry of Health via  
<https://sideeffects.health.gov.il>

You may also report to the registration holder, Novartis Israel LTD. at:  
[safetydesk.israel@novartis.com](mailto:safetydesk.israel@novartis.com)

This document has been determined by the Ministry of Health and the content therefore has been checked and approved on August 2021



## Gilenya<sup>®</sup> (FINGOLIMOD): Pregnancy - Specific Patient Reminder Card

RMP 2021-009-ENG



6 Tozeret Haaretz street, P.O.Box 7126, Tel Aviv Tel: 03-9201111, Fax: 03-9229230

## BEFORE STARTING GILENYA TREATMENT

Before taking Gilenya, tell your doctor if you are pregnant or are planning to become pregnant.

Gilenya may harm your unborn baby.

At treatment start and then regularly, your doctor will inform you about the risk and required actions to minimize this risk.

A pregnancy test should be conducted.

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 Gilenya Patient and Caregiver Guide provided by your doctor.

## WHILE YOU ARE TAKING GILENYA

While on treatment women should not become pregnant.

Patients should use effective contraception while taking Gilenya.

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

Pregnancy tests should be repeated at suitable intervals

Your doctor will provide regular counselling about Gilenya's serious risks to the fetus.

If you become pregnant or if you want to become pregnant, please discuss this with your doctor because Gilenya treatment should be discontinued.

## WHILE YOU ARE TAKING GILENYA

In the event of a pregnancy your doctor will provide counselling.

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

An ultrasonography examination should be performed, and Gilenya treatment may be discontinued

## AFTER STOPPING GILENYA 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 Gilenya due to pregnancy.

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

For further information, please read the Patient Information Leaflet Prior to use of the product.

