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MAYZENT[®] (SIPONIMOD): **INFORMATION FOR FEMALE PATIENTS OF** **CHILDBEARING POTENTIAL**

Contact details of your doctor:

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

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

RMP 2021-006-ENG



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BEFORE STARTING MAYZENT (SIPONIMOD)

Mayzent should not be used in pregnant women or in women of childbearing potential not using effective contraception.

Before starting treatment, a pregnancy test must be conducted in women of childbearing potential and a negative result verified by a doctor.

Talk with your doctor about reliable methods of birth control that you should use during treatment and for at least 10 days after you stop Mayzent treatment.

For further information, please read the Patient Information Leaflet and the Patient and Caregiver Guide prior to use of the product.

WHILE YOU ARE TAKING MAYZENT

While on Mayzent you must not become pregnant.

You must use effective methods of birth control during treatment and for at least 10 days after you stop treatment.

If you plan to become pregnant, please talk with your doctor as you will need to stop Mayzent treatment. Your doctor will provide counselling about potential risks of Mayzent to the foetus, and will discuss the possible return of disease activity with you.

Tell your doctor immediately if you become pregnant while taking Mayzent because treatment will have to be stopped. Your doctor will discuss the possible return of disease activity with you.

You will also be provided with follow-up medical examinations (e.g. ultrasonography examination).

WHILE YOU ARE TAKING MAYZENT

Should a pregnancy occur during treatment with Mayzent please report it to your doctor immediately.
contact details of your doctor:

or to Novartis by sending an E-mail to safetydesk.israel@novartis.com.
Novartis has put in place a **PR**egnancy outcomes Intensive Monitoring (**PRIM**) program to collect information about pregnancy in patients exposed to Mayzent immediately before or during pregnancy and on infant outcomes 12 months post delivery.

AFTER STOPPING MAYZENT

Effective methods of birth control should be used for at least 10 days after you stop Mayzent treatment.

Should a pregnancy occur within 10 days following discontinuation of treatment please report it to your doctor (contact details of your doctor: _____) or to Novartis by sending an E-mail to safetydesk.israel@novartis.com irrespective of adverse outcomes observed.

Novartis has put in place a **PR**egnancy outcomes Intensive Monitoring (**PRIM**) program to collect information about pregnancy in patients exposed to Mayzent immediately before or during pregnancy and on infant outcomes 12 months post delivery.

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 Mayzent.

