MAYZENT® (siponimod)▼: Information for female patients of childbearing potential

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

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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 contraception that you should use during treatment and for at least 10 days after you stop MAYZENT® treatment.

Please read the MAYZENT® information leaflet provided by your doctor

While you are taking MAYZENT®

While taking MAYZENT® you must not become pregnant.

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

If you plan to become pregnant, or if you become pregnant, please talk with your doctor as you will need to stop MAYZENT® treatment. Your doctor will provide counselling about the potential risks to the foetus that MAYZENT® can cause, and discuss the possible return of disease activity upon stopping MAYZENT® treatment.

Should a pregnancy occur during treatment with MAYZENT®, your doctor may advise for 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 (refer to page 7 for contact details) or to Novartis by calling +356 21222872 or visit www.report.novartis.com or email to: drug_safety.malta@novartis.com

Novartis has put in place a **PRegnancy 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 immediately (refer to page 7 for contact details) or to Novartis by calling +356 21222872 or visiting www.report.novartis.com or email to: drug_safety.malta@novartis.com, irrespective of adverse outcomes observed.

- Novartis has put in place a **PRegnancy 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®.

Contact details of your doctor

Name of prescriber .....

Address .....

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Telephone No of prescriber .....

Suspected Adverse Drug Reactions (side effects) and medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at http://www.medicinesauthority.gov.mt/adrportal and sent by post or email to;

P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann. SGN 3000.

E: postlicensing.medicinesauthority@gov.mt.

Healthcare Professionals may also report any adverse events associated with the use of **Mayzent** to Novartis Pharma Services Inc., Representative Office, Malta, by phone on +356 21222872, online on www.report.novartis.com or by e-mail at drug_safety.malta@novartis.com.

Marketing Authorization Holder: Novartis Europharm Limited, Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland.
Local Representative: Novartis Pharma Services Inc., Representative Office Malta.
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