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

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Contents

Before starting MAYZENT®

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. It must be repeated at suitable time intervals.

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 siponimod treatment.

Please read the MAYZENT® information leaflet included in the package.

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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 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, or you think you are 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).

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While you are taking MAYZENT®

Should a pregnancy occur during treatment with MAYZENT®, please report it to your doctor (refer to page 7 for contact details) or to Novartis by calling +356 21222872 or visiting www.novartis.com/report 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 infant outcomes 12 months post delivery

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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 (refer to page 7 for contact details) or to Novartis by calling +356 21222872 or visiting www.novartis.com/report 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 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®.

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Contact details of your doctor

- Name:.....
- Address:.....
- Telephone number:.....

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Suspected Adverse Drug Reactions (side effects) or 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 +35621222872,online on www.novartis.com/report 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. Tel No.: +356 21222872

For electronic copies of this Educational Material, please refer to the Malta Medicines Authority website - http://www.medicinesauthority.gov.mt/rmm - and download the required material with the latest date.

This educational material is a part of the conditions of the Marketing Authorisation.

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