Mayzent® Siponimod:

Information for female patients of childbearing potential

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Contents

Before starting Mayzent® Siponimod

Mayzent® Siponimod 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 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 Mayzent® Siponimod treatment.

Please read the Mayzent® Siponimod information leaflet included in the package.

While you are taking Mayzent® Siponimod

While on Mayzent® Siponimod 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® Siponimod 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® Siponimod 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® Siponimod

Should a pregnancy occur during treatment with Mayzent® Siponimod, please report it to your doctor and to Novartis by visiting https://www.novartis.com/report or by emailing seguridad.clinica@novartis.com

Novartis has put in place a PRegnancy outcomes Intensive Monitoring (PRIM) program to collect information about pregnancy in patients exposed to Mayzent® Siponimod immediately before or during pregnancy and infant outcomes 12 months post delivery

After stopping Mayzent® Siponimod

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

Should a pregnancy occur within 10 days following discontinuation of treatment please report it to your doctor and to Novartis by by visiting https://www.novartis.com/report or by emailing seguridad.clinica@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® Siponimod immediately before or during pregnancy and infant outcomes 12 months postpost-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® Siponimod.

Risk Management Plan V 7.2

For Central America and the Caribbean: "Material for exclusive use by the prescribed patient."

For CANDEAN: Go to the following link to view the importer's information:
https://www.novartis.com/candean-es/informacion-del-importador

For ACC: For more information, please contact the Novartis Medical Information department: informacion.medica@novartis.com. If you wish to report an adverse event, please visit the following link: http://www.novartis.com/report.

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