

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.



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

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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 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® treatment.

Please read the MAYZENT® information included in the package.

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 upon stopping MAYZENT® treatment.



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. ultrasound examination).



Should a pregnancy occur during treatment with MAYZENT®, please report it to your doctor, Novartis or to the TGA. You can report to Novartis by calling 1800 671 203 (Australia) or by email to patientsafety.aunz@novartis.com. Pregnancies can also be reported at www.tga.gov.au/reporting-problems.

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.

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 Neurologist, Novartis or to the TGA. You can report to Novartis by calling 1800 671 203 (Australia) or by email to patientsafety.aunz@novartis.com. Pregnancies can also be reported at www.tga.gov.au/reporting-problems.

- 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®.

Contact details of your doctor

Name:

Phone:

Email:



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