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. If you get any side effects, talk to your doctor, pharmacist or nurse. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie By reporting side effects, you can help provide more information on the safety of this medicine. Adverse events should also be reported to Novartis Ireland by calling 01-2080 612 or by email to drugsafety.dublin@novartis.com

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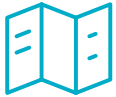
Before starting MAYZENT®

MAYZENT® must not be used in pregnant women or in women of childbearing potential not using effective contraception.

Women of childbearing potential must have a negative pregnancy test and be using effective contraception before starting treatment.

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 leaflet included in your medication 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.

Your doctor will provide counselling before treatment initiation and regularly thereafter about the potential risks to the unborn baby that MAYZENT® can cause.

If you plan to become pregnant, or if you become pregnant, please talk to your doctor about stopping MAYZENT® treatment and the possible return of disease activity upon stopping treatment.

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.

Should a pregnancy occur during treatment with MAYZENT®, your doctor may advise follow-up medical examinations (e.g. ultrasonography examination).

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.

Should a pregnancy occur during treatment with MAYZENT®, please report it to your doctor or to Novartis by calling 01 2080 612 or via www.report.novartis.com, or by email to drugsafety.dublin@novartis.com.

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, 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®.

Please see the "Patient Information Leaflet" for more information.

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