# MAYZENT® ▼ (siponimod):

## Information for female patients of childbearing potential

▼ This medicinal product is subject to additional monitoring. For more information, please see back page.

NOVARTIS

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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 and you must use effective methods of contraception.
A pregnancy test should be repeated at suitable intervals during MAYZENT® 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).

# After stopping MAYZENT®

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

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®.

# If you become pregnant during or after stopping treatment with MAYZENT®

Should a pregnancy occur during treatment or occur within 10 days following discontinuation of treatment with MAYZENT®, please report it to your doctor immediately, and all pregnancies should be reported to Novartis Patient Safety via **uk.patientsafety@novartis.com** or **0845 601 1387**.

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.

# Reporting of side effects

If you get side effects with any medication you are taking, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the information leaflet that comes in the pack.

You can also report the side effect. It is easiest and quickest to report side effects online via the Yellow Card website **https://yellowcard.mhra.gov.uk/** or search for MHRA Yellow Card in the Google Play or Apple App Store.

# Reporting of side effects

Alternatively, prepaid Yellow Cards for reporting are available by writing to **FREEPOST YELLOW CARD** (no other address details necessary), by emailing **yellowcard@mhra.gov.uk**, at the back of the British National Formulary (BNF), by telephoning the Commission on Human Medicines (CHM) free phone line: **0800 731 6789**, or by downloading and printing a form from the Yellow Card section of the MHRA website.

By reporting side effects you can help provide more information on the safety of your medication.

All pregnancies should be reported to Novartis Patient Safety via **uk.patientsafety@novartis.com** or **0845 601 1387**.

▼ 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. See www.mhra.gov.uk/yellowcard for how to report side effects.

For further information please contact Medical Information:

01276 698370 or medinfo.uk@novartis.com

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