MAYZENT®▼ (siponimod):

Information for female patients of childbearing potential

Information on how to report side effects (adverse reactions) can be found on page 6.

▼ The medicine referred to in this material 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.

This booklet is for UK patients who have already been prescribed Mayzent (siponimod). This booklet has been created by Novartis Pharmaceuticals UK Limited.

NOVARTIS

UK | March 2024 | 318331
Approved by MHRA 03-April-2024

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 included in the package.

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 will stop Mayzent immediately and 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 **01276 698370** (standard call charge applies).

Novartis has put in place a **PRegnancy outcomes Intensive Monitoring (PRIM)** programme 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.

Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme. You can report via:

- the Yellow Card website **www.mhra.gov.uk/yellowcard**
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.

When reporting please provide as much information as possible. By reporting side effects, you can help provide more information on the safety of this medicine.

All pregnancies should be reported to Novartis via **uk.patientsafety@novartis.com** or by calling 01276 698370 (standard call charge applies).

UK | March 2024 | 318331
Approved by MHRA 03-April-2024