

Patient and Caregiver Guide:

Important things to remember about your MAYZENT[®]▼ (siponimod) treatment

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.

▼ 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.

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/SystemOne/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).

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

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Introduction

This guide contains important information about Mayzent (siponimod) dosing, side effects and their potential risks, including guidance on pregnancy.

Before you start your treatment, read this guide and the leaflet, which is inside your Mayzent medication package, thoroughly. The package leaflet contains additional information on the potential side effects.

Save this guide together with the package leaflet in case you need to refer to it during treatment. Tell any doctor you see that you are being treated with Mayzent.

Use the medication schedule on page 11 when you start treatment with Mayzent.

What is MS (multiple sclerosis)?

Multiple sclerosis (MS) is a neurological disease that affects the brain and spinal cord.

In patients with MS, the body's own immune cells mistakenly attack nerve cells in the brain and spinal cord. Over time, these nerve cells are lost, leading to increasing disability.

For some people, symptoms gradually worsen from the beginning of the disease following a progressive pattern (progressive MS), but for others they come and go (relapsing-remitting MS).

Within ten years more than 50% of patients with relapsing-remitting MS will eventually develop sustained worsening of symptoms, independent of relapses, which results in disability. This is called secondary progressive multiple sclerosis (SPMS).

What Mayzent is and how it works

Mayzent contains an active substance called siponimod, which is a sphingosine-1-phosphate (S1P) receptor modulator.

It is used to treat adults with active SPMS disease.

Mayzent works by stopping the body's own immune cells (white blood cells) from travelling into the brain and spinal cord and attacking nerve cells.

Before you take Mayzent

Testing and getting ready for treatment

Before you start treatment, your doctor will perform a blood or saliva test (buccal swab) to determine how well Mayzent is broken down in your body in order to determine the most appropriate dose for you. In certain cases, the test will show that Mayzent is not the right treatment option for you.

Your blood will also be tested to check your white blood cell count and your liver function, if these have not been measured recently (within the last 6 months).

Your doctor will perform a skin examination to check for any skin nodules.

If you have not previously had chickenpox or if you can't remember if you've had it, please tell your doctor. If you are not protected against this virus, you will need a vaccination before you start treatment with Mayzent. If this is the case, your doctor will delay the start of treatment with Mayzent until one month after the full course of vaccination is completed.

Testing and getting ready for treatment

Tell your doctor if you have, or have previously had, visual disturbances or vision problems in the centre of the eye (macular oedema), inflammation or infection of the eye (uveitis), or if you have high blood sugar levels (diabetes). If you have a history of any of these conditions, your doctor may suggest you have an eye examination before you can start treatment with Mayzent.

If you have an underlying heart problem or are taking medication that can cause your heart rate to slow down, your doctor will take your blood pressure and do a test called an electrocardiogram (ECG) to check the rhythm of your heart before starting treatment with Mayzent. Your doctor may also refer you to a heart specialist (cardiologist) for advice on how you should start treatment with Mayzent, and how you should be monitored.

Before starting treatment, a pregnancy test must be conducted in women of childbearing potential, and a negative result verified by a doctor.

Before you take Mayzent

Other medication

Tell your doctor if you are taking, have recently taken or might take any other medicines. This includes any medicines that alter your immune system or medication that can cause your heart rate to slow down.

You may have to change or temporarily stop your usual medication for a short period of time. This is because the effects of these medicines can be increased when used together with Mayzent.

Mayzent is not recommended if you have certain cardiac conditions or are taking other medicines known to decrease heart rate.

The first time you take Mayzent

Slow heart rate

At the beginning of treatment, Mayzent may temporarily cause the heart rate to slow down or become irregular, which can make you feel dizzy or lightheaded. For most patients, the heart rate returns to normal within 10 days.

- You should not drive or use machinery on your first day of treatment with Mayzent, as you may feel dizzy.

Inform your doctor immediately if you experience dizziness, vertigo, nausea, fatigue or palpitations after your first dose or during the first five days of treatment.

If you have an underlying heart problem, your doctor may ask you to stay at the doctor's office or hospital for at least 6 hours after taking the first dose so that your blood pressure can be checked and an electrocardiogram (ECG) can be performed to check the rhythm of your heart. If your ECG shows any abnormalities during this time, you may need to be monitored for a longer period of time (possibly overnight) until these have resolved.

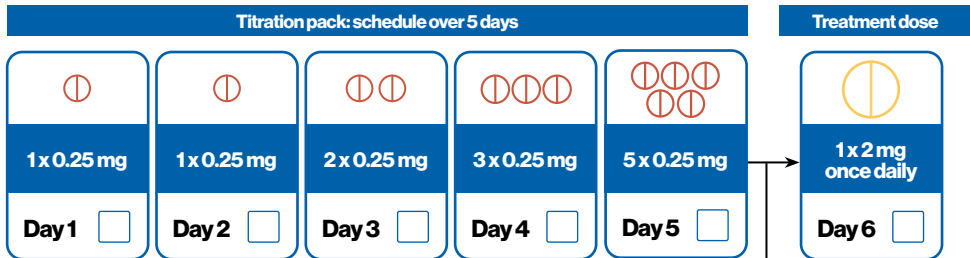
Starting treatment with Mayzent

Your treatment will start with a five-day titration pack. You will start with a dose of 0.25 mg (1 tablet) on Days 1 and 2, followed by 0.5 mg on Day 3 (two tablets), 0.75 mg on Day 4 (three tablets) and 1.25 mg on Day 5 (five tablets), to reach the recommended treatment dose (either 2 mg or 1 mg depending on the results of your blood or saliva test performed before the start of treatment) from Day 6 onward.

Gradually increasing the dose of Mayzent over a period of 5 days helps to reduce the temporary effect on your heart at the beginning of your treatment.

Take your Mayzent tablets once a day. For the first 6 days, it is recommended that you take your tablets in the morning. Take your tablets with or without food.

Mayzent medication schedule



You can use the check boxes in the image above to record the progress of your treatment or set a reminder on your mobile phone.

It's important to remember to take the tablets every day. During the first 6 days of treatment, if you forget to take a dose on one day, call your doctor immediately because treatment needs to be re-started again with a new titration pack.

*Treatment dose depends on the results of your blood or saliva test performed before the start of treatment

Forgetting to take your tablets and stopping the medication

DO NOT RESTART TREATMENT WITH YOUR REGULAR DOSE IF:

- You forget to take your treatment on any day during the first 6 days of your treatment
- You forget your treatment for 4 or more days in a row when on your prescribed treatment dose

If either of the above situations occur, treatment will need to be restarted with a new titration pack, including first dose monitoring in patients with certain heart problems. Contact your doctor to arrange restarting your treatment.

If you miss a dose when you are on the regular treatment dose (Day 7 onwards), take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and continue as usual.

Stopping treatment with Mayzent

Do not stop taking Mayzent or change your dose without talking to your doctor first.

After stopping treatment with Mayzent inform your doctor immediately if you believe disease symptoms are getting worse (e.g., weakness or visual changes) or if you notice any new symptoms.

During treatment with Mayzent

Blood tests

Your blood cell count should be checked 3 to 4 months after you have started Mayzent and then at least once a year.

Your doctor will also perform additional blood tests if there is any suspicion of an infection.

Side effects and important risks: visual symptoms

Mayzent may cause swelling at the back of the eye. This condition is known as macular oedema and is reversible if caught early.

Possible symptoms may include:

- Blurry or wavy vision, or shadows in the centre of the eye
- Vision loss or a blind spot
- Colours appearing faded or changed

Your doctor may request an eye examination before you start treatment with Mayzent and during treatment.

Tell your doctor immediately about any changes in your vision, during treatment and up to one month after you have stopped treatment with Mayzent.

Side effects and important risks: infections

Because Mayzent affects the immune system, you may be more vulnerable to infections. If you have any symptoms of an infection during treatment, and up to one month after stopping treatment, let your doctor know straight away.

Possible symptoms of a serious fungal or viral infection (e.g., meningitis and/or encephalitis) are:

- Headache accompanied by a stiff neck
- Sensitivity to light
- Fever
- Flu-like symptoms
- Nausea
- Rash
- Shingles
- Confusion
- Seizures (fits)

If you experience any weakness, changes in vision or develop new/worsening symptoms of MS, then talk to your doctor as soon as possible. These may be due to a very rare brain infection called progressive multifocal leukoencephalopathy (PML) which can occur in patients taking medicines like Mayzent and other medicines used for treating MS.

Side effects and important risks: liver damage

Mayzent can cause abnormal results in liver function tests.

Contact your doctor if you notice symptoms such as:

- Unexplained nausea
- Vomiting
- Abdominal pain
- Fatigue
- Rash
- Yellowing of the eyes or the skin
- Dark urine

These symptoms could be signs of liver problems and you should contact your doctor who will perform a liver function test.

Side effects and important risks: malignancies

Whilst you are treated with Mayzent, there is an increased risk of skin malignancies.

You should limit your exposure to the sun and UV rays, and protect yourself by wearing appropriate clothing and regularly applying sunscreen with a high degree of UV protection.

You should not receive phototherapy with UV-B radiation or PUVA-photochemotherapy (treatments used for some skin conditions) whilst you are being treated with Mayzent.

Inform your doctor immediately if you notice any skin nodules (e.g., shiny, pearly nodules), patches or open sores that do not heal within weeks. Symptoms of skin cancer may include abnormal growth or changes of skin tissue (e.g., unusual moles) with a change in colour, shape or size over time.

Your doctor will carry out regular skin examinations as you start treatment, and thereafter while on treatment with Mayzent.

Side effects and important risks: neurological and psychiatric symptoms/signs

If you have worsening of a neurological condition, or any of the following unexpected neurological or psychiatric symptoms during treatment, and up to one month after stopping treatment, tell your doctor immediately:

- Sudden onset of severe headache
- Confusion
- Seizures
- Vision changes

These may be symptoms of a condition called posterior reversible encephalopathy syndrome (PRES).

Female patients

You must avoid becoming pregnant while taking Mayzent because there is a risk of harm to the unborn baby. You will need to have a negative pregnancy test before starting treatment and at regular intervals.

Talk with your doctor about reliable methods of birth control that you should use during Mayzent treatment and for at least 10 days after you stop treatment.

Your doctor will provide counselling before treatment and regularly thereafter about the potential risks to the foetus that Mayzent can cause, and discuss the possible return of disease activity upon stopping Mayzent treatment.

Mayzent must not be used if you are pregnant or if you are a woman of childbearing potential who is not using effective contraception.

Female patients

If you get pregnant during treatment, or within 10 days following discontinuation of treatment with Mayzent, let your doctor know immediately.

Women receiving Mayzent should not breastfeed, because of the potential serious side effects for infants.

If you are a female of childbearing potential, you will also receive the Pregnancy Reminder Card.

Vaccines

Live vaccines such as tuberculosis (BCG), measles, yellow fever and rotavirus should be avoided while taking Mayzent and for 4 weeks after stopping treatment.

Vaccinations may be less effective if administered during treatment.

Talk to your doctor if you need to be vaccinated. Your treatment might have to be stopped for 1 week before vaccination and re-initiated again with a titration pack one month after vaccination.

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. 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.

Please see **www.mhra.gov.uk/yellowcard** for instructions on how to report side effects. Alternatively, you can call **0800 731 6789** for free, Monday to Friday between 9am and 5pm.

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

Contact details of your doctor

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