

▼ 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](http://www.tga.gov.au/reporting-problems).

# Patient and Caregiver Guide

Important things to remember about  
your MAYZENT<sup>®</sup> (siponimod) treatment



If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the Consumer Medicines Information (CMI) .



<b>Introduction</b>	<b>4</b>
<b>What is MS (multiple sclerosis)</b>	<b>5</b>
<b>What is MAYZENT<sup>®</sup> and how it works</b>	<b>6</b>
<b>Before you take MAYZENT<sup>®</sup></b>	<b>7</b>
<b>The first time you take MAYZENT<sup>®</sup></b>	<b>10</b>
<b>Starting your treatment with MAYZENT<sup>®</sup></b>	<b>11</b>
<b>MAYZENT<sup>®</sup> medication schedule</b>	<b>12</b>
<b>During treatment with MAYZENT<sup>®</sup></b>	<b>13</b>
<b>Side effects and important risks</b>	<b>14</b>
<b>Female patients</b>	<b>19</b>
<b>Forgetting to take your tablets and stopping the medication</b>	<b>20</b>
<b>Stopping your treatment with MAYZENT<sup>®</sup></b>	<b>21</b>
<b>Contact details of your doctor</b>	<b>22</b>

## Introduction

This guide contains important information about MAYZENT<sup>®</sup> (siponimod) dosing, side effects and their potential risks, including guidance on pregnancy.

Before you start your treatment, read this guide and the Consumer Medicines Information (CMI), which is inside your MAYZENT<sup>®</sup> medication package, thoroughly. The CMI contains additional information on the potential side effects.

Save this guide together with the CMI in case you need to refer to it during treatment. Tell any doctor you see that you are being treated with MAYZENT<sup>®</sup>.

Use the medication schedule on page 11 when you start treatment with MAYZENT<sup>®</sup>.



**If you get any side effects, it's important that you report these to your doctor. This includes any possible side effects not listed in the Consumer Medicines Information (CMI).**

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

In people living 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).

If left untreated, up to 80% of people with relapsing-remitting MS are at risk of developing secondary progressive MS; however, with appropriate treatment, this risk is much lower.<sup>2</sup>

## What is MAYZENT® and how it works



MAYZENT® contains an active substance called siponimod, which is a sphingosine-1-phosphate (S1P) receptor modulator.<sup>1</sup>

It is used to treat adults with secondary progressive multiple sclerosis.

MAYZENT® works by stopping the body's own immune cells from travelling into the brain and spinal cord and attacking nerve cells.<sup>1</sup>

A large phase 3 trial found that MAYZENT® could slow down the effects of disease activity, such as worsening disability, brain lesions and relapses.



## Testing and getting ready for treatment

Before you start treatment, your doctor will perform a blood test 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 may show that MAYZENT® is not the right treatment option for you.

Your blood may also be tested to check your blood cell count and function of your liver 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.



**Talk to your doctor if you haven't had chickenpox or if you are not sure if you have had it. 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.**

## Before you take MAYZENT®



### Testing and getting ready for treatment

Your doctor will organise an eye examination before you start MAYZENT® and at 3 to 4 months after the start of MAYZENT® treatment. Tell your doctor if you have, or have previously had, eye or vision problems (macular oedema), inflammation or infection of the eye (uveitis), or if you have high blood sugar levels (diabetes).



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.

Tell your doctor if you have severe respiratory or breathing problems.  
Your asthma medicines will be checked by your doctor.



## Other medication

Tell your doctor if you are taking medicines that lower 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 heart problems or are taking other medicines known to slow your heart rate.**

## The first time you take MAYZENT®



### Slow heart rate

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

- You should not drive or use machines during the first day of treatment initiation with MAYZENT®, as you may feel dizzy.

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

If you have underlying heart problems, your doctor may ask you to stay at the doctor's office for 6 hours or more after taking the first dose so that your blood pressure and pulse can be checked regularly 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 your treatment with MAYZENT®



Your treatment will start with a five-day titration pack with a dose of 0.25 mg on Days 1 (one tablet) and 2 (one tablet), 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 test performed before the start of treatment) from Day 6 onward.

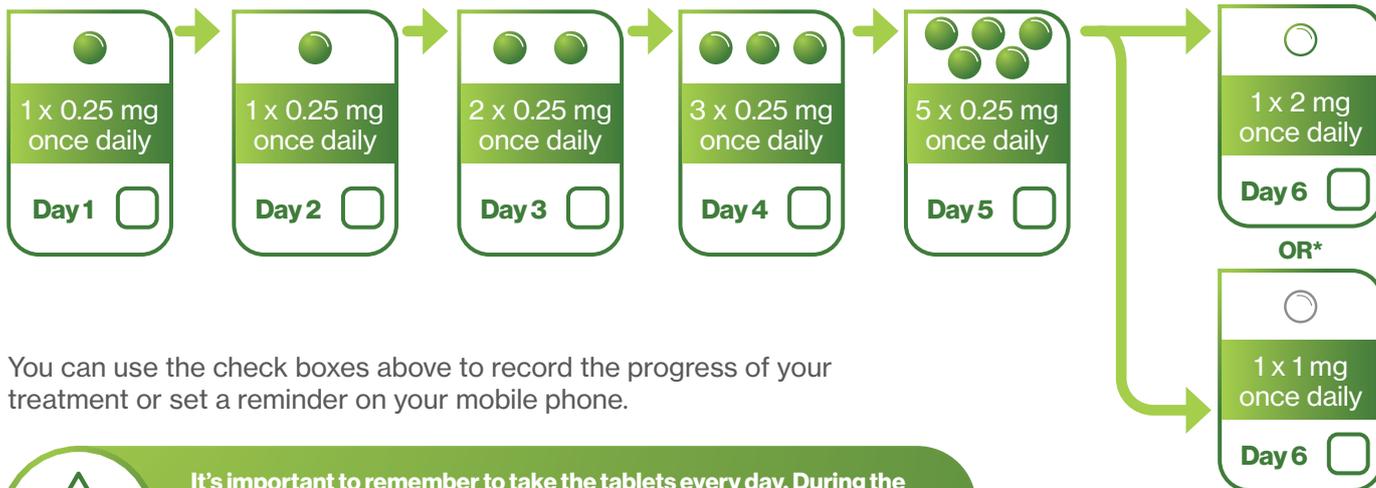
Gradually increasing the dose of MAYZENT® over a period of time helps to reduce the effect on your heart at the beginning of your treatment.

Take your MAYZENT® tablets once a day. Ideally, this should be at the same time each day, such as in the morning, and with or without food. For the first 6 days, it is recommended that you take your tablets in the morning.

# MAYZENT® medication schedule

Titration pack: Treatment schedule over 5 days

Treatment dose



You can use the check boxes 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 reinitiated again with a new titration pack.**

\*Treatment dose depends on the result of your blood test performed before the start of treatment.



## Blood tests

Once you have started treatment with MAYZENT®, you will have regular blood tests to measure your blood cell count. It is recommended that these are carried out every 3–4 months for the first year, and then once a year after that.

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 in the centre of the eye
- Vision loss
- 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 and up to one month after you have stopped treatment with MAYZENT®.**



### Infections

Because MAYZENT® affects the immune system, you may be more vulnerable to infections. If you have any of the following symptoms 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 believe your MS is getting worse, or if you notice any new symptoms during or after treatment with Mayzent, such as changes in mood or behaviour, new or worsening weakness on one side of the body, changes in vision, confusion, memory lapses, or speech and communication difficulties, call your doctor right away. These may be signs of a rare brain infection called progressive multifocal leukoencephalopathy (PML). Your doctor will monitor you for a related inflammatory reaction called immune reconstitution inflammatory syndrome (IRIS), which can occur in patients with PML as the medicine is cleared from your body.**

## Side effects and important risks



### Liver function

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 immediately contact your doctor, who may perform a liver-function test.**



### Malignancies

Whilst you are treated with MAYZENT<sup>®</sup>, there is an increased risk of skin cancers. 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<sup>®</sup>. 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<sup>®</sup>.

## Side effects and important risks



### Neurological and psychiatric symptoms/signs

Inform your doctor of any unexpected neurological or psychiatric symptoms/signs (such as sudden onset of severe headache, confusion, seizures and vision changes) or worsening of neurological condition.



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 treatment and for at least 10 days after you stop treatment.

If you get pregnant, or think you might be pregnant, during treatment, or within 10 days following discontinuation of treatment with MAYZENT®, let your doctor know immediately.

If you are a female of childbearing potential, you will also receive the Information for Female Patients of Childbearing Potential.

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

## Forgetting to take your tablets and stopping the medication



Do not restart treatment with the regular dose:

**If during the first 6 days of your treatment you forget to take a dose on any day**

OR

**If your treatment is interrupted for 4 or more days in a row when on your prescribed treatment dose**

**Treatment will need to be reinitiated with a new titration pack, including first dose monitoring in patients with certain heart problems. Contact your doctor to arrange the restart of your treatment.**

## Stopping your treatment with MAYZENT®



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

## Contact details of your doctor

Name: .....

Phone: .....

Email: .....

## Reporting adverse events

- If you get any side effects, it's important that you report these to your doctor
- This includes any possible side effects not listed in the package leaflet
- Side effects can be reported to Novartis by calling 1800 671 203 or by email to **patientsafety.aunz@novartis.com**
- Side effects can also be reported to the TGA at **[www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems)**

**References:** 1. MAYZENT® approved Product Information. Novartis Pharmaceuticals Australia Pty Ltd. 2. MS Australia. News: What determines conversion to secondary progressive MS? 21 September 2019. Available at [www.msaustralia.org.au/news/conversion-to-secondary-progressive-ms/](http://www.msaustralia.org.au/news/conversion-to-secondary-progressive-ms/) (accessed January 2026).





**Novartis Pharmaceuticals Australia Pty Limited.**  
ABN 18 004 244 160. Sydney, NSW.  
©2026 Novartis Pharmaceuticals Australia Pty Limited.  
NOMA37136M. AU-29340. January 2026.