Mayzent™

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I using Mayzent?

Mayzent contains the active ingredient siponimod. Mayzent is used for the treatment of adult patients with secondary progressive multiple sclerosis (SPMS).

For more information, see Section 1. Why am I using Mayzent? in the full CMI.

2. What should I know before I use Mayzent?

Do not use if you have ever had an allergic reaction to Mayzent or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.
For more information, see Section 2. What should I know before I use Mayzent? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Mayzent and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Mayzent?

- You start Mayzent treatment with a starter titration pack that lasts for 5 days.
- On Day 6, you take your prescribed dose. The usual dose is one 2mg tablet taken once a day.

More instructions can be found in Section 4. How do I use Mayzent? in the full CMI.

5. What should I know while using Mayzent?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Mayzent.

	• Have a blood test to check genotype and for complete blood count before starting Mayzent • Have an eye check up before starting Mayzent • Tell your doctor if you plan to receive a vaccine • Have regular skin checks and protect your skin from sun exposure • Avoid becoming pregnant while using Mayzent and for 10 days after you stop using it
Things you should not do	• Do not stop using this medicine suddenly.
Driving or using machines	• It is not known if Mayzent will influence your ability to drive and use machines.
Drinking alcohol	• There are no known interactions between Mayzent and alcohol
Looking after your medicine	Refrigerate, do not freeze. Store between 2°C – 8°C for the 0.25mg, 1mg and 2mg tablets. After opening, only the 1mg and 2mg

	tablets can be stored below 30°C for up to 3 months. • Keep out of reach of children

For more information, see Section 5. What should I know while using Mayzent? in the full CMI.

6. Are there any side effects?

Common side effects include headache, dizziness, diarrhoea, feeling unwell, pain in arms/legs, weakness, shaking.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ 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.

Mayzent™

Active ingredient(s): *siponimod*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Mayzent. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Mayzent.**

Where to find information in this leaflet:

1. Why am I using Mayzent?
2. What should I know before I use Mayzent?
3. What if I am taking other medicines?
4. How do I use Mayzent?
5. What should I know while using Mayzent?
6. Are there any side effects?
7. Product details

1. Why am I using Mayzent?

Mayzent contains the active ingredient siponimod. Mayzent belongs to a group of medicines called sphingosine-1-phosphate (S1P) receptor modulators. Mayzent helps to slow down the effects of multiple sclerosis (MS) such as worsening disability and decline in thinking. It may also slow down the nerve damage caused by MS and increase your time without relapse.

Mayzent is used for the treatment of adult patients with secondary progressive multiple sclerosis (SPMS).

2. What should I know before I use Mayzent?

Warnings

Do not use Mayzent if:

- you are allergic to siponimod, or any of the ingredients listed at the end of this leaflet.

  Always check the ingredients to make sure you can use this medicine.
- you have the CYP2C9 *3*3 genotype
- in the last 6 months, you have had a heart attack, angina, stroke or certain types of heart failure.
- you have irregular or abnormal heartbeat (arrhythmia) and you do not have a pacemaker.

Check with your doctor if you:

- have CYP2C9 *3*3 genotype (less than 0.4 to 0.5% of the population).Your doctor will do a blood test to check this before you start Mayzent.
- have not had a recent blood test. A complete blood count should be done before starting Mayzent.
- have an infection
- have a lowered immune system (due to a disease or take medicines that lower your immune system) and may get infections more easily
- have not had chickenpox or have not been vaccinated against chicken pox
- plan to receive a vaccine. You should not receive certain vaccines (called live attenuated vaccines) during treatment with Mayzent and for up to 4 weeks after stopping treatment with Mayzent.
- have or have had eye problems or vision problems. Your doctor will organise an eye check up before you start Mayzent and then regular eye check ups.
- have uncontrolled high blood pressure
- have a slow heartbeat or are taking medicines that can slow your heartbeat
- have severe breathing problems or asthma
- have liver problems. Your doctor will do a blood test to check your liver function before you start Mayzent.
- have any other medical conditions
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Your doctor will discuss with you what is best for you and your baby.

If you become pregnant or think you are pregnant, tell your doctor right away.

You should not take Mayzent while you are breastfeeding. Talk to your doctor if you are breastfeeding or intend to breastfeed.

Contraception

You should avoid becoming pregnant while using Mayzent and for at least 10 days after you stop using it. Ask your doctor or pharmacist for options of effective birth control.

Use in children

Mayzent has not been studied in patients below 18 years old.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Mayzent and affect how it works.

- Medicines for an irregular heartbeat such as quinidine, procainamide, amiodarone or sotalol.
- Medicines that slow down your heartbeat such as verapamil or diltiazem, ivabradine or digoxin.
- Medicines that affect the immune system such as other medicines used to treat multiple sclerosis, or corticosteroids.
- Certain types of vaccines (called live attenuated vaccines).
- A medicine called carbamazepine.
- Medicines such as modafinil, efavirenz and fluconazole if you have a certain genotype.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Mayzent.

4. How do I use Mayzent?

How much to take

Your Mayzent treatment will start with a titration pack that lasts for 5 days. You take the following tablets:

Titration	**Titration dose**	**Titration regimen**
Day 1	0.25 mg	1 tablet of 0.25 mg Mayzent
Day 2	0.25 mg	1 tablet of 0.25 mg Mayzent
Day 3	0.5 mg	2 tablets of 0.25 mg Mayzent
Day 4	0.75 mg	3 tablets of 0.25 mg Mayzent
Day 5	1.25 mg	5 tablets of 0.25 mg Mayzent

- On Day 6, you take your prescribed dose. The usual dose is one 2mg tablet taken once a day.
- For some patients that have a CYP2C9 *2*3 or CYP2C9 *1*3 genotype, the usual dose is 1 mg once daily.

Follow the instructions provided, and take Mayzent until your doctor tells you to stop.

When and how to take Mayzent

- Take Mayzent once a day at about the same time each day.
- Swallow the tablets with half a glass of water. You can take Mayzent with or without food.

If you forget to take Mayzent

Mayzent should be taken regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then take the next tablet as usual.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you missed a dose on one day during first 6 days of treatment, call your doctor before you take the next dose. Your doctor will need to prescribe a new starter titration pack. You will have to restart at Day 1 with a new starter titration pack.

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

If you stop taking Mayzent for 4 or more repeated daily doses, you need to re-start treatment with the starter titration pack.

If you take too much Mayzent

If you think that you have taken too much Mayzent, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Mayzent?

Things you should do

- Have regular eye check ups
- Have regular skin checks and protect your skin from sun exposure
- Tell your doctor if you plan to receive a vaccine

Avoid becoming pregnant while using Mayzent and for 10 days after you stop using it.

Call your doctor straight away if you:

- develop any type of infection
- notice any skin changes or sores
- believe your multiple sclerosis is getting worse or if you notice any new or unusual symptoms. A rare brain infection called progressive multifocal leukoencephalopathy (PML) can cause symptoms similar to SPMS. PML can occur in patients taking medicines like Mayzent and other medicines used for treating MS. If you have PML, your doctor will stop treatment with Mayzent. Some people with PML may have a reaction as Mayzent is removed from the body. This reaction (known as immune reconstitution inflammatory syndrome or IRIS) may lead to your condition getting worse.
- get a fever, feel like you have a flu, or have a headache with a stiff neck, sensitivity to light, feel sick, and feel confused (as these may be caused by a viral or fungal infection).

Remind any doctor, dentist or pharmacist you visit that you are taking Mayzent.

Things you should not do

- Do not stop using this medicine suddenly.

If you stop taking Mayzent, symptoms of multiple sclerosis can return and may become worse compared to before or during treatment. Keep taking Mayzent unless your doctor tells you to stop.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Mayzent affects you.

Mayzent may cause dizziness in some people.

Looking after your medicine

- Store the tablets in a refrigerator (between 2 to 8°C). Do not freeze.
- After opening, only the 1mg and 2mg tablets can be stored below 30°C for up to 3 months (in a cool dry place away from moisture, heat or sunlight). Keep in the original package.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
General such as: • Headache • Dizziness • Diarrhoea • Feeling unwell • Pain in legs or arms • Swollen hands, ankles, legs or feet • Weakness • Skin changes such as small spots or lumps of colours ranging from blue/dark to brown, pink to skin coloured.	**Speak to your doctor if you have any of these less serious side effects and they worry you.** **If these side effects become severe, please tell your doctor, pharmacist or healthcare provider**

Serious side effects

Serious side effects	What to do
Infections such as:	**Call your doctor straight away, or go straight to the Emergency**

Serious side effects	What to do
• Shingles - a painful rash of small fluid-filled blisters appearing on reddened skin, tingling burning sensation • Fever, sore throat or mouth ulcers. • Fungal or viral - headaches with a stiff neck, sensitivity to light, feeling sick, and feeling confused • Weakness or visual changes, memory loss, trouble thinking or difficulty walking (signs of a rare brain infection called progressive multifocal leukoencephalopathy which can then develop into immune reconstitution inflammatory syndrome). **Heart issues such as:** • Slow heartbeat • Irregular heartbeat. **Skin cancer:**	**Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
• Raised, smooth, shiny pink or pearly bump on the skin (basal cell carcinoma). • Scaly or red raised patch, or wart like sore, or a new sore on an existing scar (squamous cell carcinoma). • New moles or moles that change size, shape, height or colour over time (malignant melanoma). **Worsening of multiple sclerosis symptoms such as:** • muscle weakness, muscle stiffness, muscle spasms • eye changes such as blurred vision, double vision • tremor • general weakness or • any unusual or different symptoms. **General:**	

Serious side effects	What to do
• Difficulty breathing • Convulsions, uncontrolled shaking of the body • Blurred vision, trouble seeing colours • Unexplained nausea, vomiting with abdominal pain, fatigue, yellowing of the skins or eyes, dark urine. • Allergic reactions, including rash or itchy skin, swelling of lips, tongue or face.	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Some side effects can only be found when your doctor does tests from time to time to check your progress. These include:

- Higher levels of liver enzymes
- Changes to your blood cell counts
- Changes to the health of your eyes
- Abnormal changes to your skin.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Mayzent contains

Active ingredient **(main ingredient)**	siponimod
Other ingredients **(inactive ingredients)**	Tablet core: Lactose monohydrate microcrystalline cellulose crospovidone colloidal anhydrous silica glycerol dibehenate.

	Tablet coating: Polyvinyl alcohol titanium dioxide iron oxide yellow (2 mg tablet) iron oxide red black iron oxide (0.25 mg and 1mg tablet) purified talc lecithin (soya) xanthan gum.
Potential allergens	Lactose Sugars as lactose

Do not take this medicine if you are allergic to any of these ingredients.

What Mayzent looks like

Mayzent is supplied as film-coated tablets in blister packs.

Mayzent 0.25 mg tablets are: pale red, round, biconvex-beveled edged film-coated tablet with Novartis logo on one side and T on other side (AUST R 310498). Each pack contains 12 tablets (titration pack) or 120 tablets.

Mayzent 1 mg tablets are: violet white, round biconvex-beveled edged film-coated tablet with Novartis logo on one side and L on other side. (AUST R 395451). Each pack contains 28 tablets.

Mayzent 2 mg tablets are: pale yellow, round, biconvex-beveled edged film-coated tablet with Novartis logo on one side and II on other side (AUST R 310499). Each pack contains 28 tablets.

Who distributes Mayzent

Mayzent is supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

Level 25, Victoria Cross Tower

155 Miller Street

North Sydney NSW 2060

Telephone 1 800 671 203

Web site: www.novartis.com.au

Mayzent is supplied in New Zealand by:

NOVARTIS New Zealand Ltd

PO Box 99102, Newmarket

Auckland 1149, New Zealand

Telephone: 0800 354 335

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