

Treatments for MS:

Siponimod (Mayzent®)

There is a range of disease modifying therapies approved for people with MS in Australia. These therapies, also called immunotherapies, work to reduce disease activity in the central nervous system in people with MS.

What is siponimod and how does it work?

Siponimod (brand name Mayzent®) is used for the treatment of adults with secondary progressive MS (SPMS), the form of MS that can follow on from relapsing remitting MS. People with SPMS experience a gradual worsening of their condition as disability accumulates.

Siponimod acts on certain types of white blood cells (lymphocytes) which are involved in the immune attack on myelin seen in MS. It binds to special locations (or receptors) on the surface of the lymphocytes, called sphingosine-1-phosphate receptors (S1P-R). This causes lymphocytes to be retained in the lymph glands. As a result, the number of lymphocytes circulating in the blood and reaching the brain is decreased, resulting in reduced immune attack on nerve cells in the brain and spinal cord.

How is siponimod (Mayzent®) administered?

Siponimod (Mayzent®) is taken as a film-coated tablet, once daily.

Before initiation of treatment with Mayzent® the CYP2C9 genotype of the patient should be determined to inform whether a 2mg or 1mg maintenance dose is required. Mayzent® should not be used in patients with the more rare CYP2C9*3*3 genotype. Patients will not be charged for the costs of the genotype test. Also, before treatment with Mayzent® a blood test will be taken to check the level of white blood cells in the patient and to check the patient's liver function, due to the increased risk of infection or worsening of an existing infection.

Treatment has to be initiated with a titration pack that lasts for 5 days. The dose titration starts with 0.25 mg once daily on day 1 and 2, followed by once daily doses of 0.5 mg on day 3 (two tablets of 0.25 mg), 0.75 mg on day 4 (three tablets of 0.25 mg), and 1.25 mg on day 5 (five tablets of 0.25 mg), to reach the maintenance dose of 2 mg Mayzent® starting on day 6.

The recommended maintenance dose is 1 mg daily for patients with CYP2C9 *2*3 or *1*3 genotype (for further information on maintenance dosing please see the Consumer Medicine Information). During the first 6 days of treatment initiation, the recommended daily dose should be taken once daily in the morning with or without food.

What are the possible side effects of siponimod (Mayzent®)?

Siponimod (Mayzent®) helps most people with SPMS, but it may have unwanted side effects in some people. All medicines can have side effects. Tell your doctor if you notice anything that is making you feel unwell.

The most important side effects of siponimod (Mayzent®) include headache, high blood pressure and increases in liver function tests. It may increase the risk of infections, may cause macular edema (swelling in the back of the eye) and may cause transient decreases in heart rate and a decline in lung function.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. You should avoid becoming pregnant while taking Mayzent® and for at least 10 days after you stop taking it. You should not breast-feed while taking Mayzent®.

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

Siponimod (Mayzent®) has not been studied in patients below 18 years.

How much does siponimod (Mayzent®) cost?

Siponimod (Mayzent®) was approved by the Therapeutic Goods Administration (TGA) on 1 November 2019 for the treatment of adults with secondary progressive multiple sclerosis (SPMS) in Australia.

In December 2019, siponimod (Mayzent®) was **not** recommended for listing on the Pharmaceutical Benefits Scheme (PBS) by the Pharmaceutical Benefits Advisory Committee (PBAC). More information is available from <https://www.pbs.gov.au/pbs/industry/listing/elements/pbac-meetings/pbac-outcomes>.

Siponimod is not currently marketed in Australia.

MS Australia will continue to work with Novartis, the PBAC and the Australian Government to progress a listing for this treatment in the future.

General information

In Australia, siponimod (Mayzent®) is supplied by:

Novartis Pharmaceuticals Australia Pty Ltd

54 Waterloo Road

North Ryde NSW 2113 Australia

For more information on MS and other MS treatments

- Speak to your neurologist about what treatment best suits your individual circumstances.
 - MS Nurses can also provide information, training and ongoing support in managing your immunotherapy.
 - For information about MS, MS treatment and to find contact details for your state MS organization visit www.msaustralia.org.au
 - MS Research Australia provides information on the latest research and clinical trials at www.msra.org.au
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References:

1. [MS Trust UK](https://mstrust.org.uk/a-z/siponimod) – mstrust.org.uk/a-z/siponimod
2. [MS Research Australia news item regarding siponimod](#), including links to and details regarding the clinical trials
3. [Consumer Medicine Information](#) - <https://www.tga.gov.au> (search for siponimod)

Note:

MS Australia does not recommend any specific disease-modifying treatment for people living with MS. Decisions about any treatments, taking into consideration the potential benefits and side effects for each individual's circumstances, should be made in careful consultation with the person's neurologist.

The information supplied in this document is collated from material provided by the relevant pharmaceutical company, and MS Research Australia.