Information for people living with multiple sclerosis

Treatment

Mayzent® (siponimod)

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Mayzent® (siponimod)

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

What is Mayzent® and how does it work?

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

Mayzent® acts on certain types of white blood cells (lymphocytes) which are involved in the immune attack on myelin seen in multiple sclerosis. It binds to special locations (or receptors) on the surface of the lymphocytes, called sphingosine-1-phosphate (S1P) receptors. This causes lymphocytes to be retained in the lymph nodes. 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.

Mayzent® is also able to enter the central nervous system where it can bind to S1P receptors on certain brain cells involved in repairing or slowing down the damage caused by multiple sclerosis.

How is Mayzent® administered?

Mayzent® is a film-coated tablet taken orally, once daily. Before initiation of treatment with Mayzent® a person's CYP2C9 genotype should be determined to inform whether a 2mg or 1mg maintenance dose is required. Mayzent® should not be used in people with the more rare CYP2C9*3*3 genotype. People considered for Mayzent® will not be charged for the costs of the genotype test. Also, before treatment with Mayzent® a blood test may be taken to check the level of white blood cells and liver function. Treatment has to be initiated with a titration pack that lasts for 5 days. The dose titration starts with 0.25mg once daily on day 1 and 2, followed by once daily doses of 0.5mg on day 3 (two tablets of 0.25mg), 0.75mg on day 4 (three tablets of 0.25mg), and 1.25mg on day 5 (five tablets of 0.25mg), to reach the maintenance dose of 2mg Mayzent® starting on day 6. The recommended maintenance dose is 1mg daily for people with the 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 Mayzent®?

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 Mayzent® include headache, high blood pressure and increases in liver function tests. It may increase the risk of infections, may cause macular oedema (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, plan to become pregnant or are breastfeeding. You should avoid becoming pregnant while taking Mayzent® and for at least 10 days after you stop taking it. You should not breastfeed 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.

Mayzent® has not been studied in patients under 18 years.

How much does Mayzent® cost?

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 July 2020, Mayzent® was recommended for listing on the Pharmaceutical Benefits Scheme (PBS) by the Pharmaceutical Benefits Advisory Committee (PBAC) for patients with secondary progressive multiple sclerosis who are ambulant (with or without support). More information is available from **https://www.pbs.gov.au/pbs/industry/listing/elements/pbac-meetings/pbac-outcomes**.

When Mayzent® is listed on the PBS, patients will need to pay the standard PBS co-payments. Recommendations by the PBAC for the listing of medicines on the PBS are subject to final approval by the Australian Government, which is yet to occur for this treatment.

Mayzent® (siponimod)

General information

In Australia, Mayzent® is supplied by:
Novartis Pharmaceuticals Australia Pty Ltd
54 Waterloo Road
Macquarie Park NSW 2113

For more information on multiple sclerosis and other multiple sclerosis 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 multiple sclerosis, multiple sclerosis 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**

References

1. **Consumer Medicine Information** - **https://www.tga.gov.au** (search for Mayzent)
2. Mayzent® Approved Product Information, Nov 2019
3. **MS Research Australia news item regarding siponimod**, including links to and details regarding the clinical trials

Note

MS does not recommend any specific disease-modifying treatment for people living with multiple sclerosis. 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.