



Treatments for MS:

Gilenya[®] (fingolimod)

There are currently several disease-modifying therapies approved for people with MS in Australia. These therapies, called immunotherapies, work to reduce disease activity in the central nervous system and reduce the frequency and severity of relapses in people with MS.

What is Gilenya and how does it work?

Gilenya belongs to a class of medications called sphingosine 1-phosphate (s1P) receptor modulator. The active ingredient in Gilenya is fingolimod.

Gilenya acts on certain types of white blood cells called lymphocytes. In multiple sclerosis, these small lymphocyte cells play a role in destroying myelin, the protective sheath that surrounds the nerve fibres and helps with the efficient flow of nerve signals or messages to and from the brain and various parts of the body.

Gilenya helps prevent lymphocytes leaving the lymph nodes. This lowers the number of

Lymphocytes circulating in the blood and reaching the central nervous system, which in turn reduces damage to the nerve cells in the brain and spinal cord.

Gilenya has been shown in clinical trials to:

- Reduce the frequency of relapses
- Delay progression of physical disability

There is also evidence it may have a direct effect in enhancing remyelination of damaged nerve cells.

How is Gilenya administered?

Gilenya is taken in capsule form (0.5mg), once a day. The first dose of Gilenya is given in a doctor's office or clinic, where the person is observed for six hours to monitor heart rate and any adverse side effects. Following the initial

dose, the person takes one capsule each day. If Gilenya therapy is discontinued for more than two weeks and reintroduced, the same process used for initial dosing is applied.

How is Gilenya supplied?

Gilenya is available through an *Authority Prescription* from your neurologist. Gilenya comes in a box which contains 28 gel capsules. Each capsule contains 0.5mg of the active ingredient, fingolimod.

Gilenya needs to be stored at room temperature (below 30C) and away from moisture.

Not all pharmacies keep Gilenya in stock, however, most are able to order it for you if you notify them a few days before you need it.

In Australia, Gilenya is supplied by Novartis Australia.

How much does Gilenya cost?

Gilenya is approved under the Pharmaceutical Benefits Scheme (PBS) which means the cost of this medication is subsidised by Medicare Australia. If you are eligible for medications through the PBS, you still need to pay a patient contribution each time your prescription is dispensed.

For more information about the PBS speak to your pharmacist or visit

www.medicareaustralia.gov.au

What are the potential side effects of Gilenya?

Gilenya was generally well tolerated by participants in clinical trials. The most common side effects included headache, influenza, infection, diarrhea, back pain, abnormal liver, enzyme levels and coughing. Less common but potentially serious side effects included slow heart rate (when starting treatment), breathing difficulties, increased risk of infection, and macular oedema (swelling in the back of the eye).

To reduce the risk of people developing any one of these serious side effects and to ensure that they are identified as quickly as possible in people who develop them, there are strict safety protocols in place. These include a number of screening tests before you are prescribed Gilenya and an observation period after your

initial capsule. Your neurologist or clinic staff can provide you with more information about this process.

Your doctor or pharmacist can provide comprehensive information on the safe use of Gilenya, precautions and a complete list of common and more serious side effects. Gilenya has not been tested in people under the age of 18 or in women who are pregnant or breastfeeding; therefore the side effects are unknown in these groups. Despite the clinical trials, the safety, tolerability and efficacy of Gilenya beyond two years and any long-term side effects are still unknown. The prescription of Gilenya is based on strict criteria and the medical opinion and close supervision of a treating neurologist.

For more information:

- Speak to your neurologist about what treatment best suits your individual circumstances.
 - MS Research Australia (MSRA) provides information on the latest research and clinical trials in MS. Visit www.msra.org.au for more information.
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For information about MS and MS Australia services:

Call MS Connect: 1800 042 138

Web: www.msaustralia.org.au

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