MS PLUS
Neuro Wellbeing

Information for people living with multiple sclerosis

Treatment

Gilenya® (fingolimod)

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There is a range of disease-modifying therapies approved for people living with multiple sclerosis in Australia. These therapies, also called immunotherapies, work to reduce disease activity in the central nervous system and reduce the frequency and severity of relapses in people living with multiple sclerosis.

What is Gilenya® and how does it work?

Gilenya® belongs to a class of medications called sphingosine 1-phosphate (s1P) receptor modulators. 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.

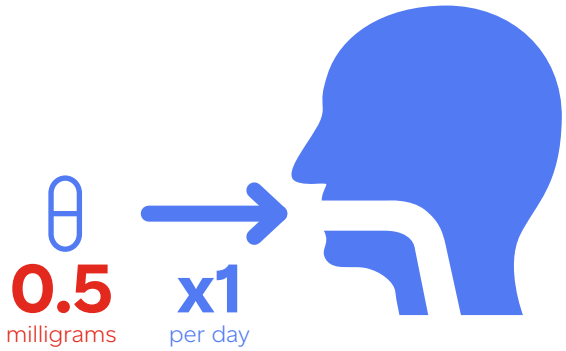
Gilenya® has been shown in clinical trials[5] to have significant beneficial effect in adults and children of 10 years of age and above, with relapsing-remitting multiple sclerosis (RRMS) by:

- Reducing the frequency of relapses when compared to placebo and interferon-beta-1-a [1, 2, 3, 4]
- Delaying progression of physical disability when compared to placebo [1, 4]
- Improved MRI outcomes when compared to placebo and interferon-beta-1-a [1, 2, 3, 4]
- Showing a lower rate of brain volume loss when compared to interferon-beta-1-a[3, 4]

How is Gilenya® administered?

Gilenya® is taken orally in capsule form, once a day. The dosage is 0.5mg for adults and children over 40kg in weight; for children weighing 40kg or under the dose is 0.25mg.

The first dose of Gilenya® is given in a doctors' 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. Similarly, for a child moving from the 0.25mg dose (40kg and under) to the 0.5mg dose (once above 40kg), the six-hour observation is repeated for their first 0.5mg dose.



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, basal cell carcinoma, increased risk of infection including isolated cases of cryptococcal meningitis, macular oedema (swelling in the back of the eye) and isolated seizure cases in children.

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.

Progressive Multifocal Leukoencephalopathy (PML) can be associated with taking Gilenya®. PML is a life threatening brain infection caused by the John Cunningham virus (JC virus) which manifests in people whose immune system has been supressed. PML has also been associated with other immunosuppressive medications for multiple sclerosis.

Since the rate of PML in people taking Gilenya® is very low, no formal safety protocols are in place. Prescribing information has been updated to ensure clinicians are alert to the possibility of PML in patients taking Gilenya®.

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 women who are pregnant or breastfeeding; therefore the side effects are unknown and use of Gilenya® is contraindicated in these groups. The prescription of Gilenya® is based on strict criteria and the medical opinion and close supervision of a treating neurologist. Please discuss with your neurologist whether Gilenya® is the right treatment for you.

How much does Gilenya® cost?

Both dosages of Gilenya® have been approved by the Therapeutic Goods Administration (TGA) for use in Australia. The 0.5mg capsule is available through the Pharmaceutical Benefits Scheme (PBS). Your neurologist will need to obtain an authority to prescribe the medication for you.

For details of the criteria required to receive a prescription for Gilenya® treatment through the PBS, please visit the official PBS website at: **www.pbs.gov.au/medicine/item/5262Y** You will need to click on the red **Authority Required (STREAMLINED)** link.

If you are eligible for medications through the PBS, you will need to pay a contribution fee each time your prescription is dispensed. The Federal Government pays the remaining cost. The amount of the contribution fee depends upon whether or not you have a pension or concession card. The amount of this fee is set each year by the Federal Government.

Further information about the PBS, your entitlements and details regarding the PBS safety net (which protects patients and their families requiring a large number of PBS items) is available through the Medicare Australia website at: **www.medicare.gov.au**

If you are not eligible for Gilenya® through the PBS, for example if you are a visitor from overseas, or you require the 0.25mg dose, your neurologist may write a private prescription. In this instance you will have to pay the full cost to the pharmacy that dispenses your medication. You may wish to request a quote from your pharmacist for the price of any medication which is not subsidised by the PBS.

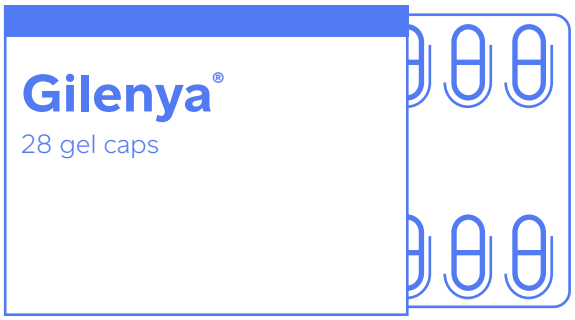
General information

Gilenya® comes in a box which contains 28 gel capsules. Each capsule contains either 0.5mg or 0.25mg of the active ingredient, fingolimod.

Gilenya® needs to be stored at room temperature (below 30°C) 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
54 Waterloo Road
North Ryde NSW 2113



<30°C
Storage temperature

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.
- We can provide emotional and practical support for every stage of your journey. For more information visit **www.msplus.org.au**
- For more information about multiple sclerosis treatments, research, clinical trials and for your state MS organisation visit **www.msaustralia.org.au**

References

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2. Cohen, JA, et al. N Engl J Med. Oral Fingolimod or Intramuscular Interferon for Relapsing Multiple Sclerosis. 2010; 362:402-15
3. Cohen, JA, et al. J Neurol Neurosurg Psychiatry. Long-term (up to 4.5 years) treatment with fingolimod in multiple sclerosis: results from the extension of the randomised TRANSFORMS study. 2015;0:1-8
4. Chitnis, T, et al. N Engl J Med. Trial of Fingolimod versus Interferon Beta-1a in Pediatric Multiple Sclerosis. 2018; 379:1017-27
5. Gilenya® Approved Product Information, April 2019 **www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2011-PI-01890-3&d=201905071016933**

Note

MS Plus 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 Australia.