

Treatments for MS:

Tecfidera[®] (dimethyl fumarate)

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 and reduce the frequency and severity of relapses in people with MS.

What is Tecfidera[®] and how does it work?

Tecfidera[®] - previously known as BG-12 - is an oral treatment for Australian patients with relapsing-remitting multiple sclerosis (MS).

Tecfidera[®] has been shown to have anti-inflammatory and neuro-protective properties.

It is thought that Tecfidera[®] works in MS by inhibiting immune cells and molecules, and may have anti-oxidant properties that protect the brain and spinal cord from damage¹. Clinical trials² have shown it can reduce relapse rates and delay the progression of disability in people with relapsing remitting MS.

How is Tecfidera[®] administered?

Tecfidera[®] is taken as an oral capsule. The recommended starting dose of Tecfidera[®] is 120mg, twice daily. After 7 days the dose may be increased to the recommended dose of 240mg twice daily. Tecfidera[®] can be taken with or without food. For patients who experience gastrointestinal side-effects, taking the capsules during a meal may reduce these side-effects. For patients who experience flushing, taking aspirin before their Tecfidera[®] dose may reduce this side-effect.

What are the potential side effects of Tecfidera[®]?

In clinical trials of Tecfidera[®], the most common side-effects experienced were flushing, diarrhea, nausea and abdominal pain. Less common but more serious side-effects include more severe gastrointestinal side-effects, effects on the kidneys and liver, and reduced white blood cell counts.

Progressive Multifocal Leukoencephalopathy (PML) can be associated with taking Tecfidera[®]. PML is a life threatening brain infection caused by the JC virus which manifests in people whose immune system has been suppressed. PML has also been associated with other immunosuppressive medications for MS. It is recommended that patients on Tecfidera[®] have their white blood cell counts monitored prior to beginning treatment and every three months during treatment, to ensure levels are safe.

Tecfidera[®] has not been tested in people under the age of 18 or in women who are pregnant or breastfeeding. Women who are pregnant, planning pregnancy or breastfeeding should seek advice from their doctor.

How much does Tecfidera® cost?

Tecfidera® has been approved by the Therapeutic Goods Administration (TGA) and is listed on the Pharmaceutical Benefits Scheme. Please consult your neurologist to see if Tecfidera® is the right treatment for you.

For details of the criteria required to receive a prescription for Tecfidera® treatment through the PBS, please visit the official PBS website at:

<http://www.pbs.gov.au/medicine/item/2896K-2943X> - 120mg

<http://www.pbs.gov.au/medicine/item/2966D> - 240mg

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 for 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 Tecfidera® through the PBS, for example if you are a visitor from overseas, your neurologist may write a private prescription. You will have to pay the full cost to the pharmacy that dispenses your medication. The cost is likely to be over \$1000 per month.

You will need to request a quote from your pharmacist for the price of any medication which is not subsidised by the PBS.

General Information

Most pharmacies do not keep Tecfidera® in stock. Instead they will place an order with the manufacturer to have stock delivered especially for you. It is therefore important to let your pharmacist know a few days before you need the medication.

Tecfidera® is manufactured by:

Biogen Australia Pty Ltd

Level 3

123 Epping Road

North Ryde

NSW 2113

Ph: 02 8875 3900

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. Scannevin RH, et al. Fumarates promote cytoprotection of central nervous system cells against oxidative stress via the nuclear factor (erythroid-derived 2)-like 2 pathway. *Journal of Pharmacology and Experimental Therapeutics* 2012;341:274-84.
 2. Tecfidera® Approved Product Information, February 2017
<https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2013-PI-01953-1>
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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, MIMS (<http://www.mims.com.au>) and MS Research Australia.