

Treatment

MAVENCLAD[®] (cladribine tablets)

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There is a range of disease-modifying therapies approved for people living with relapsing-remitting 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 MAVENCLAD® and how does it work?

The active ingredient of MAVENCLAD® is cladribine. It is used for the treatment of patients living with relapsing-remitting multiple sclerosis to reduce inflammation in the nervous system caused by multiple sclerosis.

In multiple sclerosis, the immune system mistakenly attacks the protective layer (myelin) around the nerve cells. This causes inflammation and damage

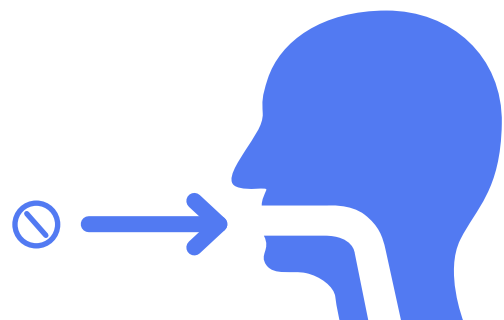
which stops the nervous system working properly. By reducing the number of destructive immune cells in circulation, cladribine may slow down or stop the immune attack.

In relapsing-remitting multiple sclerosis, MAVENCLAD® has been shown to result in fewer relapses, less disease activity in the brain and less progression of disability.

How is MAVENCLAD® administered?

MAVENCLAD® is administered in two treatment courses over two years. Each treatment course consists of two treatment weeks. For a treatment week, you will be prescribed to take one or two tablets, once a day for four to five days. There is no MAVENCLAD® treatment between the two courses. Your doctor will decide the number of tablets per day (one or two) and number of treatment days (four or five) depending on your body weight. You may need to take the same number of tablets each day or some days you might take two tablets and then only one tablet on the following days.

No further MAVENCLAD® treatment is required in years three and four. Re-initiation of therapy after four years has not been studied.



What are the possible side effects of MAVENCLAD®?

MAVENCLAD® helps most people living with multiple sclerosis, 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 effect of MAVENCLAD® is a reduction in the number of a type of white blood cell known as lymphocytes. This is very common in patients on MAVENCLAD® treatment and may be severe. Reduced lymphocytes may increase your risk of getting an infection, particularly viral infections.

Other common side effects include: cold sores, shingles, skin rashes and a reduced neutrophil count (a common type of white blood cell important to fighting off infections).

Symptoms of shingles include a 'band' of severe pain and blistering rash, typically on one side of the upper body or the face, burning, tingling, numbness or itchiness of the skin in the affected area and feeling generally unwell or fever in the early stages of infection. Tell your doctor immediately if you get symptoms of shingles.

An independent meta-analysis found no conclusive evidence for an increased risk of malignancy with MAVENCLAD® in trials of licensed disease modifying drugs or placebo-controlled trials.

Progressive Multifocal Leukoencephalopathy (PML) is a rare, life-threatening brain infection caused by the John Cunningham virus (JC virus), which manifests in people whose immune system has been suppressed. Although there were no cases of PML associated with MAVENCLAD® use in clinical trials, PML has been associated with other immunosuppressive medications for multiple sclerosis. Some of the symptoms of PML are similar to multiple sclerosis. Your neurologist will assist you to assess the risks and the expected benefit of treatment with MAVENCLAD® prior to starting therapy and over the course of treatment.

MAVENCLAD® is not recommended for patients who have a hypersensitivity to the active substance, have an infection with HIV or active chronic infections (tuberculosis, hepatitis), are immunocompromised, have an active malignancy, have moderate or severe renal impairment, or are pregnant or breastfeeding. Women who are planning a pregnancy should speak to their doctor.

How much does MAVENCLAD[®] cost?

MAVENCLAD[®] has been approved by the Therapeutic Goods Administration (TGA) for the treatment of patients with relapsing remitting MS and 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 Mavenclad[®] treatment through the PBS, please visit the official PBS website at: <https://www.pbs.gov.au/medicine/item/11603Q-11604R-11611D-4326Q-7225G>. 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 MAVENCLAD[®] through the PBS, for example if you are a visitor from overseas, 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 will need to request a quote from your pharmacist for the price of any medication which is not subsidised by the PBS.

General information

In Australia, MAVENCLAD® is supplied by:

Merck Serono Australia Pty Ltd
Unit 3-4, 25 Frenchs Forest Road
Frenchs Forest NSW 2086

Medical Information: 1800 633 463 (1800 MED INF)

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

1. MAVENCLAD® Approved Product Information, www.tga.gov.au/ 2017
2. MS Trust UK: www.mstrust.org.uk/a-z/cladribine-mavenclad

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.