Treatments for MS:

MAVENCLAD® (cladribine tablets)

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

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

In MS, 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 RRMS, 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 4-5 days. There is no MAVENCLAD® treatment between the two courses. Your doctor will decide the number of tablets per day (1 or 2) and number of treatment days (4 or 5) 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 3 and 4. Re-initiation of therapy after 4 years has not been studied.

What are the possible side effects of MAVENCLAD®?

MAVENCLAD® helps most people with MS, 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 JC virus, which manifests in people whose immune system has been supressed. **Although there were no cases of PML associated with MAVENCLAD® use in clinical trials, PML has been associated with other immunosuppressive medications for MS.** Some of the symptoms of PML are similar to MS. 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 that 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 relapsing remitting multiple sclerosis (RRMS) to reduce the frequency of clinical relapses and to delay the progression of physical disability.

MAVENCLAD® was recommended for listing on the Pharmaceutical Benefits Scheme (PBS) by the Pharmaceutical Benefits Advisory Committee (PBAC) in August 2018. Its listing on the PBS is subject to final approval by the Federal Health Minister.

Please consult your neurologist if you are interested in this medication to see if MAVENCLAD® is the right treatment for you.

General information

In Australia, MAVENCLAD® is supplied by:

Merck Serono Australia Pty Ltd

Unit 3-4, 25 Frenchs Forest Road

Frenchs Forest NSW 2086 Australia

Medical Information: 1800 633 463 (1800 MED INF)

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

References:

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

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.