



**MAVENCLAD<sup>®</sup>**  
**(cladribine tablets)**

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MS Treatments

# MSology Essentials Series

MAVENCLAD<sup>®</sup>

(cladribine tablets)

Developed by MSology with the invaluable assistance of multiple sclerosis nurse advisors:

[Naomi Akazawa](#)

MS Clinic, The Ottawa Hospital, Ottawa, Ontario

[Colleen Harris](#)

MS Clinic, University of Calgary, Calgary, Alberta

[Josée Poirier](#)

MS Clinic, CR CHUM, Montreal, Quebec

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## Why treat MS?

Multiple sclerosis (MS) is believed to be caused by an abnormal immune response, which results in inflammation and tissue damage in the brain and spinal cord (together called the central nervous system, or CNS). This inflammation is the cause of MS symptoms, such as nerve tingling, muscle weakness, vision problems, balance difficulties and pain. New or worsening MS symptoms that last for more than a day or two are called relapses, and these generally indicate an inflammatory flare-up in the CNS. Relapse symptoms can persist for several weeks or months. Some relapses will resolve completely and some will not. As you experience more and more relapses, the body is unable to repair the damage to the brain and spinal cord, which typically leads to physical and mental impairments.

That is why it is so important to treat MS – to reduce inflammation and tissue damage and reduce or delay disability. The medications prescribed are called disease-modifying therapies because they target the underlying MS disease process. They do not heal any tissue damage that has already occurred, but they may prevent further damage that will contribute to disability in the years ahead.

MS medications do not treat specific symptoms, so you will not feel an improvement in the symptoms you are having. The main effects of therapy are to lessen the frequency and severity of relapses and reduce the amount of inflammation in the brain and spinal cord. So treatment can be seen as an investment in your future – lessening the often silent damage that is occurring now to prevent disabilities later on.



## How does Mavenclad work?

Mavenclad is an oral medication (pill) used to treat relapsing-remitting multiple sclerosis.

In MS, specialized cells of the immune system (called T and B cells) become activated, enter the CNS and cause inflammation and tissue damage. Mavenclad reduces the number of these inflammatory cells in your blood stream so there are fewer cells available to attack the body's own tissues. This effect on immune cells can be achieved with a short course of treatment – one week of medication followed by a second week of medication a month later.

After you've completed these two weeks of treatment, the number of immune cells will gradually return to normal levels in about a year. So a second course of treatment in Year 2 will be needed to reduce the number of immune cells once again. After the full two-year course of Mavenclad is completed, your immune system may start to reconstitute itself in a healthier way. Most people are generally observed for two years (no treatment) unless their MS becomes active again.

Clinical trials have shown that in people with MS, Mavenclad reduces the rate of relapses, lowers the risk of worsening disability and suppresses inflammatory lesions in the brain.



## How do I take Mavenclad?

### DOSING

- Mavenclad must be taken once-daily for two treatment weeks per year for two years. The dose is 1–2 pills per day (see diagram on page 4).
- The full course of treatment is 4 or 5 days of medication (in week 1), followed a month later by another 4 or 5 days of medication (in week 5). This same schedule is repeated a year later.
- The dosing of Mavenclad is unique – it's based on your personal body weight. The total amount of drug you take is 3.5 mg per kilogram of body weight over the course of two years. This means that a person who weighs more will need to take more pills than someone who weighs less. Calculating the right dose for your body is important but rest assured that your MS nurse and pharmacist will provide you with detailed instructions on how to take Mavenclad, so you receive the correct amount of medication for your body.
- Once your two weeks of treatment (in weeks 1 and 5) in Year 1 are completed, you will not need to take more medication for a year.
- Mavenclad may be taken with or without food. You may be less likely to develop a headache or nausea if you take it with food.



**Mavenclad is unique in that the dose you take will depend on your body weight. This means that the amount of drug you take is individualized to your body's needs. Before you start your second year of treatment, your nurse will weigh you – if your weight has changed, your dose will need to be adjusted accordingly.**



## CONSIDERATIONS

- Take Mavenclad at least 3 hours before or 3 hours after any other medications you take.
- Wash and dry your hands before taking Mavenclad. If you set the pill(s) down on a counter or table, wash the area thoroughly after you've taken the pill(s). Wash your hands after taking your pill(s).
- When you remove the pill(s) from the blister pack, take it immediately. Swallow the pill(s) whole with water. Do not chew the pill(s) or let it dissolve in your mouth.
- Keep Mavenclad away from children and pets
- If you forget to take a dose, do not double up on your next dose. Take your usual dose the next day, and then add a day at the end of the treatment week. So if your dosing schedule is Monday to Friday and you forget your Wednesday dose, take that Wednesday dose on Saturday.
- Mavenclad contains sorbitol so do not take it if you have a hereditary problem of fructose intolerance.

## WHEN TO TAKE MAVENCLAD

Year 1			Year 2	
Week 1	Week 5	Week 6-52	Week 1	Week 5
1-2 pills per day for 4-5 days	1-2 pills per day for 4-5 days	No treatment	1-2 pills per day for 4-5 days	1-2 pills per day for 4-5 days

After the second year, no further treatment may be required unless your MS becomes active again.



## How do I know my treatment is working?

During your course of treatment, your doctor will monitor your response to the medication with a variety of tests and procedures. These typically include neurological examinations to evaluate your nerve and muscle function, and magnetic resonance imaging (MRI) to assess the extent of inflammatory activity in your brain and spinal cord. Other tests and procedures may also be needed during your course of treatment.

## What if I have a relapse?

A *relapse* is a new MS symptom you haven't had before, or a worsening of symptoms you've previously experienced. The symptom persists for at least 24 hours. If you become overheated – from exercise, a hot bath, a fever or infection – your MS can worsen for a shorter period of time, but these symptoms are not a relapse.

You may have a relapse soon after starting treatment, especially if your MS was very active before. This doesn't mean your medication is not working. You will only experience the full benefit of your MS medication after you've taken the initial course of treatment (in weeks 1 and 5).

It's important to inform your neurologist or MS nurse if you experience a relapse or any new or worsening symptoms that last more than 24 hours.



## What are the possible side effects of this medication?

### Low blood-cell counts

Mavenclad is an immune-suppressing drug. It works by reducing the number of immune cells ('lymphocytes' or white blood cells) that cause inflammation and damage in people with MS. This is an intended effect of the drug, rather than a side effect. But it means that when you get a blood test, the results will show a low lymphocyte count. When your lymphocyte count is low, you may be more susceptible to infections (see below). To ensure that your blood-cell count doesn't get too low, you will need to have a blood test before starting Mavenclad and another blood test before the Year 2 course of treatment. Your doctor may also order additional blood tests periodically.

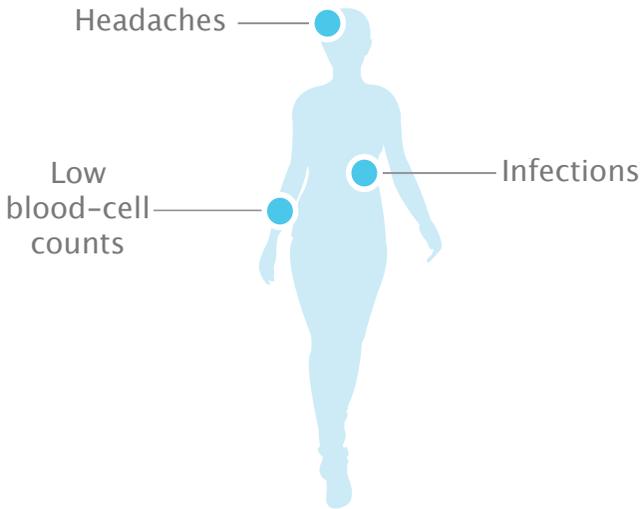
### Infections

Mavenclad suppresses your immune response so your body's ability to fight infections may be somewhat impaired. Mavenclad should not be taken by people with current infections (e.g. hepatitis, tuberculosis). The most common infections during treatment are respiratory tract infections (e.g. bronchitis), oral herpes ('cold sores'), and shingles, which is a flare-up of the chickenpox virus in people who have had chickenpox. Your doctor may prescribe an antiviral medication as a precaution against developing shingles. Progressive multifocal leukoencephalopathy (PML), a potentially fatal brain infection, can be a risk with any medication that alters the immune response; no cases of PML have occurred in people with MS treated with Mavenclad. Contact your doctor or MS clinic nurse immediately if you think you have an infection.



## Headache

If you experience a headache, take a pain reliever such as ASA (e.g. Aspirin), acetaminophen (e.g. Tylenol) or ibuprofen (e.g. Motrin, Advil) as you would for other headaches.



All medications have the potential to cause a variety of side effects. If you experience any new, unusual or worrisome symptoms while taking your medication, report them promptly to your doctor or MS nurse. Your MS nurse can provide helpful advice to minimize any unwanted medication-related effects you may experience.



You can lower your risk of infections by frequent hand-washing. During cold and flu season, try to avoid people or situations where you'll be exposed to germs. Do not travel to countries where tuberculosis or other infections are more common, or where inoculation with a live vaccine is needed.



## Tests you may need during treatment with Mavenclad.\*

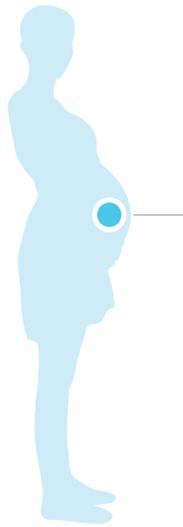
Test/procedure	Reason	How often
Blood test	To determine your complete blood cell count (CBC)	<ul style="list-style-type: none"><li>• Before starting Mavenclad</li><li>• Before taking the Year 2 course of treatment</li><li>• If you develop an infection</li><li>• Periodically according to your physician</li></ul>
Vaccination	To protect against infections	<ul style="list-style-type: none"><li>• Before starting Mavenclad your regular vaccinations (measles, mumps, rubella, tetanus) should be up-to-date</li><li>• Before starting Mavenclad you will require a varicella (chickenpox) vaccine if you have never had chickenpox</li></ul>
Pregnancy test (if applicable)	To ensure you are not pregnant	<ul style="list-style-type: none"><li>• Before starting Mavenclad</li><li>• If pregnancy is suspected during treatment</li></ul>
Skin or blood test	To ensure that you don't have tuberculosis (TB)	<ul style="list-style-type: none"><li>• Before starting Mavenclad</li></ul>
Magnetic resonance imaging (MRI)	To ensure that you don't have progressive multifocal leukoencephalopathy (PML)	<ul style="list-style-type: none"><li>• As a precaution around the time of starting Mavenclad</li><li>• This is especially important if you have previously taken another medication that has a risk of PML</li></ul>

\* Your neurologist or MS nurse will tell you more about the specific tests you'll need during treatment. Please ensure that you have all of the necessary tests at the recommended times.



## Pregnancy

Mavenclad may cause harm to a developing fetus so women and men must avoid a pregnancy for at least 6 months after their last dose of Mavenclad. Talk to your doctor or MS nurse before becoming pregnant so you can schedule the best time for you to plan a pregnancy.



Mavenclad should not be taken during pregnancy or breastfeeding

**Women and men** must use a reliable method of contraception during treatment with Mavenclad. It isn't known if Mavenclad makes birth control pills less effective, so include a barrier method of contraception (e.g. condom) for at least 4 weeks after the last dose.

Mavenclad should not be taken during pregnancy or breastfeeding. If you become pregnant after your first treatment year, your second treatment year can be postponed until the baby has been weaned.



## Other medications

All medications have the potential to interact with other drugs you are taking. This includes other prescription medications, as well as non-prescription drugs and alternative/complementary therapies.

Mavenclad should not be taken at the same time as other medications. Take Mavenclad at least 3 hours before or 3 hours after you take another medication.

Talk to a healthcare professional before taking any new medication. Your doctor, MS nurse or pharmacist can advise you about any interactions that may occur.

## Other medical conditions

Always ensure that your doctor is aware of any other medical conditions you may have. This includes high blood pressure, liver or kidney problems, diabetes, infections, or other illnesses.



## Resources in your community

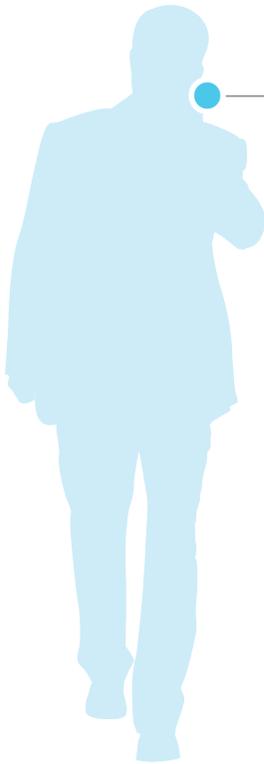
Your neurologist or MS nurse can provide you with information on the **adveva™ program**, which offers information and support for people taking Mavenclad.

Your local pharmacist can also provide important advice on your medication, how to take it, and what other medications (including non-prescription and alternative/complementary therapies) to avoid.



## Contacting your MS nurses

Contact your MS nurse if you have any questions or concerns about your medication. It is important to notify your doctor or MS nurse if you have any new, worrisome or unusual symptoms that may be related to your medication, or any worsening of your MS symptoms.



Notify your doctor or MS nurse if you have any new symptoms









The MS Essentials series provides the latest information on multiple sclerosis medications, research, and lifestyle issues such as health, nutrition and exercise. All of the booklets are developed by Lind Publishing, publishers of MSology, to help people affected by MS remain active and informed. MS Essentials is provided free of charge. The full series of publications is available for download on <http://www.MSology.com>.

The information reflects use of the medication in Canada; use may vary in other countries. MSology does not approve, endorse or recommend any specific product or therapy. Contact your healthcare providers before you start treatment, alter the dose, interrupt or discontinue your therapy. For full information about a specific medication, consult the prescribing information or package insert provided by the manufacturer for your country.



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For more multiple sclerosis information, visit [www.MSology.com](http://www.MSology.com)

