



Below is a guide to help you understand what tests your healthcare provider may perform before you start MAVENCLAD treatment. We've also included a Pre-Treatment Testing form to be filled out by your healthcare provider that can help you keep track of your tests.



Cancer screening

MAVENCLAD can't be used with patients with current malignancy. Your healthcare provider may want to conduct a standard cancer screening due to a risk of malignancies.



Pregnancy

If you are pregnant or planning on becoming pregnant prior to treatment, your healthcare provider will not prescribe you MAVENCLAD. Your healthcare provider should order a pregnancy test for you before you begin your first and second yearly treatment course of MAVENCLAD to make sure that you are not pregnant.

Both men and women should use effective birth control while taking MAVENCLAD and for at least 6 months after the last dose in year 1 and year 2.

Talk to your healthcare provider if you use birth control pills. You should use a second method of birth control on the days which you take MAVENCLAD and for at least 4 weeks after your last dose of each yearly treatment courses.

Stop treatment with MAVENCLAD and contact your healthcare provider right away if you become pregnant during treatment with MAVENCLAD.



Complete blood count (CBC)

Obtaining a CBC is important before you start MAVENCLAD. Your healthcare provider will want to make sure your lymphocytes are within normal range.



Magnetic resonance imaging (MRI)

Your healthcare provider should obtain a baseline (within 3 months) MRI before you can start your treatment of MAVENCLAD.



Infections

Because of the possible side effects of MAVENCLAD, your healthcare provider should rule out infections, such as:

- HIV
- Tuberculosis
- Hepatitis B and C
- Acute infections

Please see *Important Safety Information* on pages 5-7 of this document, and MAVENCLAD *Prescribing Information / Medication Guide*, including **serious side effects**.

PRE-TREATMENT CHECKLIST (CONT.)



Administer immunizations and vaccinations

Your healthcare provider may want to administer vaccinations prior to starting MAVENCLAD. You should not:

- Receive live or live-attenuated vaccines within 4 to 6 weeks before you start your treatment
- Receive these types of vaccines during your treatment until your healthcare provider tells you that your immune system is no longer weakened



Also, remember to let your healthcare provider know:

- ✓ If you are breastfeeding or planning on breastfeeding
- ✓ If you have heart failure
- ✓ If you have taken, currently take, or plan to take other treatments for MS
- ✓ About the medicines you take, including:
 - Prescription medicines
 - Over-the-counter medicines
 - Vitamins
 - Herbal supplements



Liver injury

MAVENCLAD may cause liver problems. So, your healthcare provider might conduct blood tests to check your liver.

PRE-TREATMENT TESTING

Date: _____ Patient: _____ / /
NAME DATE OF BIRTH

Healthcare provider: _____ () -
NAME PHONE NUMBER

Have your healthcare provider indicate what screenings/tests are needed before you begin treatment with MAVENCLAD. If you have any questions about these screenings/tests or how to complete them, please contact your healthcare provider.

Cancer screening: _____
Complete by date: _____

Blood work: _____
Complete by date: _____

Magnetic resonance imaging (MRI): _____
Complete by date: _____

Pregnancy: _____
Complete by date: _____

HIV test: _____
Complete by date: _____

Please see Important Safety Information on pages 5-7 of this document, and MAVENCLAD Prescribing Information / Medication Guide, including **serious side effects**.

Tuberculosis: _____

Complete by date: _____

Hepatitis B and C: _____

Complete by date: _____

Vaccinations: _____

Complete by date: _____

Other: _____

Complete by date: _____

Other: _____

Complete by date: _____

Comments: _____

Note to healthcare provider: Confirmation of the patient's medical clearance to begin MAVENCLAD can be indicated on the MAVENCLAD Prescriptions and Service Request Form (SRF), by faxing in a MS LifeLines Medical Clearance form to 1-781-681-2907, or providing verbal confirmation by calling MS LifeLines at 1-877-477-3243.

MS LifeLines is sponsored by EMD Serono, Inc.

Please see *Important Safety Information* on pages 5-7 of this document, and MAVENCLAD *Prescribing Information / Medication Guide*, including **serious side effects**.

Important Safety Information

What is MAVENCLAD?

MAVENCLAD is a prescription medicine used to treat relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, MAVENCLAD is generally used in people who have tried another MS medicine that they could not tolerate or that has not worked well enough.

MAVENCLAD is not recommended for use in people with clinically isolated syndrome (CIS).

It is not known if MAVENCLAD is safe and effective in children under 18 years of age and is therefore not recommended.

MAVENCLAD may cause serious side effects, including:

- **Risk of cancer (malignancies).** You should follow healthcare provider instructions about screening for cancer.
- **MAVENCLAD may cause birth defects if used during pregnancy.** Females must not be pregnant when they start treatment with MAVENCLAD or become pregnant during MAVENCLAD dosing and within 6 months after the last dose of each yearly treatment course. You should stop treatment with MAVENCLAD and contact your healthcare provider right away if you become pregnant during treatment with MAVENCLAD.
 - For females who are able to become pregnant:
 - Your healthcare provider should order a pregnancy test before you begin your first and second yearly treatment course of MAVENCLAD to make sure that you are not pregnant.
 - Use effective birth control (contraception) on the days on which you take MAVENCLAD and for at least 6 months after the last dose of each yearly treatment course.
 - Talk to your healthcare provider if you use oral contraceptives (the “pill”).

- You should use a second method of birth control on the days on which you take MAVENCLAD and for at least 4 weeks after your last dose of each yearly treatment course.
- For males with female partners who are able to become pregnant:
 - Use effective birth control (contraception) during the days on which you take MAVENCLAD and for at least 6 months after the last dose of each yearly treatment course.

Do not take MAVENCLAD if you:

- have cancer (malignancy).
- are pregnant, plan to become pregnant, or are a woman of childbearing age or a man able to father a child and you are not using birth control.
- are breastfeeding.
- are human immunodeficiency virus (HIV) positive.
- have active infections, including tuberculosis (TB), hepatitis B or C.
- are allergic to cladribine.

Before you take MAVENCLAD, tell your healthcare provider about all of your medical conditions, including if you:

- think you have an infection.
- have taken, take, or plan to take medicines that affect your immune system or blood cells, or other treatments for MS. Certain medicines can increase your risk of getting an infection.
- have had a recent vaccination or are scheduled to receive any vaccinations. You should not receive live or live-attenuated vaccines within the 4 to 6 weeks preceding treatment with MAVENCLAD or receive these types of vaccines during your treatment with MAVENCLAD and unless directed by your healthcare provider.
- have heart failure.

- have or have had cancer.
- have liver or kidney problems.
- are breastfeeding or plan to breastfeed. It is not known if MAVENCLAD passes into your breast milk. Do not breastfeed on the days on which you take MAVENCLAD, and for 10 days after the last dose.

How should I take MAVENCLAD?

- MAVENCLAD is given as two yearly treatment courses.
- Each yearly treatment course consists of 2 treatment weeks (also called cycles) that will be about a month apart.
- Take MAVENCLAD with water and swallow whole without chewing. MAVENCLAD can be taken with or without food.
- Swallow MAVENCLAD right away after opening the blister pack.
- Your hands must be dry when handling MAVENCLAD and washed well with water afterwards.
- Limit contact with your skin. Avoid touching your nose, eyes and other parts of the body. If you get MAVENCLAD on your skin or on any surface, wash it right away with water.
- Take MAVENCLAD at least 3 hours apart from other medicines taken by mouth during the 4- to 5-day MAVENCLAD treatment week.
- If you miss a dose, take it as soon as you remember on the same day. If the whole day passes before you remember, take your missed dose the next day. Do not take 2 doses at the same time. Instead, you will extend the number of days in that treatment week.

Your healthcare provider will continue to monitor your health during the 2 yearly treatment courses, and for at least another 2 years during which you do not need to take MAVENCLAD. It is not known if MAVENCLAD

is safe and effective in people who restart MAVENCLAD treatment more than 2 years after completing 2 yearly treatment courses.

MAVENCLAD can cause serious side effects. If you have any of these symptoms listed below, call your healthcare provider right away:

- **low blood cell counts** have happened and can increase your risk of infections during treatment with MAVENCLAD. Blood tests are needed before you start treatment with MAVENCLAD, during your treatment with MAVENCLAD, and afterward, as needed.
- **serious infections such as:**
 - **TB, hepatitis B or C, and shingles (herpes zoster).** Fatal cases of TB and hepatitis have happened with cladribine during clinical studies. Tell your healthcare provider right away if you get any symptoms of the following infection related problems or if any of the symptoms get worse, including: fever, aching painful muscles, headache, feeling of being generally unwell, loss of appetite, burning, tingling, numbness or itchiness of the skin in the affected area, skin blotches, blistered rash, or severe pain.
 - **progressive multifocal leukoencephalopathy (PML).** PML is a rare brain infection that usually leads to death or severe disability. Although PML has not been seen in MS patients taking MAVENCLAD, it may happen in people with weakened immune systems. Tell your healthcare provider right away if you have any new or worsening neurologic signs or symptoms. These may include: weakness on 1 side of your body, loss of coordination in your arms and legs, decreased strength, problems with balance, changes in your vision, changes in your thinking or memory, confusion, or changes in your personality.
- **liver problems.** Blood tests should be performed to check your liver before you start taking MAVENCLAD. Symptoms of liver problems may include: nausea, vomiting,

stomach pain, tiredness, loss of appetite, dark urine, or your skin or the whites of your eyes turn yellow.

- **allergic reactions (hypersensitivities).** You should stop treatment and seek immediate medical attention if any signs or symptoms of allergic reactions occur. Symptoms of an allergic reaction may include: skin rash, swelling or itching of the face, lips, tongue or throat, or trouble breathing.
- **heart failure.** MAVENCLAD may cause heart failure, which means your heart may not pump as well as it should. Call your healthcare provider or go to the closest emergency room for medical help right away if you have any signs or symptoms such as shortness of breath, a fast or irregular heart beat, or unusual swelling in your body.

The most common side effects of MAVENCLAD include: upper respiratory infection, headache, and low white blood cell counts.

These are not all the possible side effects of MAVENCLAD. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see full [Prescribing Information/ Medication Guide](#), including **serious side effects**, for additional Important Safety Information.