

MAVENCLAD® (cladribine) tablets 10 mg Patient FAQ

MAVENCLAD® (cladribine) tablets 10 mg: Information for people living with relapsing multiple sclerosis

Below are common questions and answers about treatment with MAVENCLAD. This is not a complete list of information about MAVENCLAD. If you have any questions, please contact your healthcare provider.

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INDICATION

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.

Treatment with MAVENCLAD may increase your risk of developing cancer. You should follow healthcare provider instructions about screening for cancer. Because of the risk of birth defects, do not take MAVENCLAD if you are pregnant or of childbearing potential and not using effective birth control.

Please see [Important Safety Information](#) on pages 7 through 9.

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1. Who should not take MAVENCLAD?

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.

2. What are the possible side effects of MAVENCLAD?

MAVENCLAD can cause **serious side effects, including risk of cancer (malignancies) and birth defects if used during pregnancy.**

MAVENCLAD can also cause:

- low blood cell counts
- serious infections such as:
 - life-threatening or fatal infections caused by bacteria, viruses, parasites or fungi
 - tuberculosis (TB), hepatitis B or C, and shingles (herpes zoster)
 - progressive multifocal leukoencephalopathy (PML)
- liver problems
- allergic reactions (hypersensitivities)
- heart failure

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. Please see the [Medication Guide](#) for additional information.

3. What should I know about the risk of cancer?

When taking certain disease-modifying therapies (DMTs) that suppress your immune system, including MAVENCLAD, there is an elevated risk of developing cancer.

Do not take MAVENCLAD if you have cancer (malignancy). Tell your doctor if you have or have had cancer.

You and your healthcare provider should discuss the risk of developing cancer if you take MAVENCLAD, as treatment may increase your risk. In a clinical study of patients taking MAVENCLAD, no one specific type of cancer was prevalent.

You should follow your healthcare provider's instructions about screening for cancer. This may include following standard cancer screening guidelines and monitoring before, during, and after treatment.

Please see [Important Safety Information](#) on pages 7 through 9.

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4. Does MAVENCLAD affect the immune system?

Yes, MAVENCLAD affects the immune system. Because of the short-course dosing schedule, MAVENCLAD has been shown in a clinical trial to cause temporary immunosuppression, which means it did not continuously suppress the immune system. After each treatment course and over several months, the immune cells recovered to near-normal levels. Meanwhile, other immune cells were still present to defend against infection.

Do not take MAVENCLAD if you are human immunodeficiency virus (HIV) positive or have active infections, including tuberculosis (TB), hepatitis B or C. Before you take MAVENCLAD, tell your healthcare provider about if you think you have an infection. Life-threatening or fatal infections caused by bacteria, viruses, parasites or fungi have been reported.

Your healthcare team will monitor your health and blood cell count. To read about how MAVENCLAD is thought to work with your immune system and MS, visit [HowMAVENCLADWorks.com](https://www.mavenclad.com/HowMAVENCLADWorks.com).

5. What should I know about fertility and pregnancy?

Because of the risk of birth defects, do not take MAVENCLAD® (cladribine) if you are pregnant or are of childbearing potential and not using effective birth control.

Both men and women should use effective birth control while taking MAVENCLAD and for at least 6 months after the last dose of each yearly treatment course.

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

Before starting treatment with MAVENCLAD, your doctor will complete a series of tests and ask you some important questions to check if this treatment is right for you. Please tell your doctor if you are pregnant, breastfeeding, or are planning to become pregnant.

To read more about the safety and side effects, visit [MAVENCLAD.com](https://www.mavenclad.com).

Please see [Important Safety Information](#) on pages 7 through 9.

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6. What should I know about the MAVENCLAD dosing schedule?

MAVENCLAD is prescribed for no more than 10 days a year for 2 years. The dosing schedule for Years 1 and 2 is the same. This means 1 or 2 pills per day for up to 5 days. Then about a month later, another 1 or 2 pills per day for up to 5 days. And that's it for the whole year. The number of pills you take per day will depend on your weight.

Outside of this treatment schedule, you will not take any MAVENCLAD. It will continue to treat your MS while you're not actively taking it.

Once you're prescribed treatment, your healthcare provider will monitor you before, during, and after treatment to see how you're doing. Your healthcare provider will continue to monitor your health for an additional 2 years, during which you do not have to take MAVENCLAD.

Your healthcare provider may delay or completely stop treatment with MAVENCLAD if you have severe side effects.

To learn more about the dosing schedule and taking MAVENCLAD, visit [TakingMAVENCLAD.com](https://www.takingmavenclad.com).

7. What tests will I need before and during treatment?

Some of the recommended screenings and tests before starting treatment with MAVENCLAD and at various times throughout your treatment include:

- **Cancer screening**
- **Pregnancy test**
- **Complete blood count (CBC)** before starting treatment in Years 1 and 2, and 2 months and 6 months after you start treatment in each year
- **Magnetic resonance imaging (MRI)**
- **Tests** for infections such as HIV, tuberculosis (TB), and hepatitis B and C
- **Immunizations and vaccinations**
- **Liver injury test** before each treatment cycle in Years 1 and 2

To download the pre-treatment checklist, visit [MAVENCLADChecklist.com](https://www.mavencladchecklist.com).

8. Are my routine vaccinations affected?

If you are considering treatment with MAVENCLAD, you should talk to your healthcare provider about the vaccinations you have recently had or may need. Your healthcare provider should administer live or live-attenuated vaccines at least 4 to 6 weeks prior to starting MAVENCLAD in each treatment year and only if your white blood cell counts are within normal limits. You should not receive live or live-attenuated vaccines during your treatment with MAVENCLAD or until you confirm with your healthcare provider.

Please see [Important Safety Information](#) on pages 7 through 9.

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9. How well is MAVENCLAD known to work?

MAVENCLAD was studied in a 96-week clinical trial with relapsing MS patients to measure how well it worked (efficacy) and to evaluate its safety. 433 people took MAVENCLAD and 437 people took a placebo. The clinical trial compared MAVENCLAD to placebo in 3 key ways:

Rate of relapse: A calculation that includes the number of relapses, the number of people in the study, and time studied. **Number of lesions:** This includes the number of current lesions and new lesions that developed or grew in size during the study. **Disability progression:** A measure of change in disability over a 3-month period during the study.

In this clinical study, treatment with MAVENCLAD reduced relapses, slowed progression of disability, and decreased development of new and active lesions. Of course, each person will experience different results.

Visit [MAVENCLADResults.com](https://www.mavencladresults.com) for more details.

10. What can I expect after completing the 2 yearly treatment courses?

After the 2-year, primary clinical trial was completed, 98 people from the trial participated in a follow-up study for an additional 96 weeks. During this time, they did not take any additional doses of MAVENCLAD. It's worth noting that the extension study was not a planned study, and not all patients started at the same time. At the end of the study, analyses indicated that the results were similar to the primary trial. However, it is important to know that everyone's MS is different and your experience may vary.

Your healthcare provider will continue to monitor your health for at least another 2 years after completing your second treatment course. During this time, you will not take MAVENCLAD.

11. After Year 4, will I need to take MAVENCLAD again?

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. Be sure that you and your healthcare provider talk about next steps. Your healthcare provider may continue to monitor you with no additional treatment. Or you may discuss other treatment options. Together, you and your healthcare provider can decide what treatment plan is right for you.

Please see [Important Safety Information](#) on pages 7 through 9.

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12. What financial and patient support is available?

MS LifeLines® is a patient resource sponsored by EMD Serono that provides financial and treatment support through Financial Support Specialists and MS-certified nurses.

Financial Support Specialists and MS LifeLines Nurses can help with a variety of topics or concerns that may come up before, during, and after each treatment course. In addition, information about the MS LifeLines Co-Pay Assistance Program, as well as other assistance programs, including free medication, is available. To read more details about the support provided by MS LifeLines, visit [MAVENCLADSupport.com](https://www.mavenclad.com/support).

Please see [Important Safety Information](#) on pages 7 through 9.

Indication and Important Safety Information for MAVENCLAD® (cladribine)

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. Women 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 women 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.
 - Ask your healthcare provider which contraceptive method is right for you. Women and men being treated with MAVENCLAD should use effective birth control (contraception) on the days on which they 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.

(continued)

Please see full [Prescribing Information](#) and [Medication Guide](#), including **serious side effects**.

Important Safety Information for MAVENCLAD® (cladribine) (continued)

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

- 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, consisting of two treatment weeks (cycles) about a month apart.
- Handle MAVENCLAD with dry hands and take immediately after opening the blister pack. Take with water and do not chew the tablet. MAVENCLAD can be taken with or without food and should be taken at least 3 hours apart from other medicines.
- Wash your hands after handling MAVENCLAD. Limit contact with your skin (especially on your face). Wash skin and surfaces with water if contact occurs.
- 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:**
 - **life-threatening or fatal infections caused by bacteria, viruses, parasites or fungi.**
 - **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.

(continued)

Please see full [Prescribing Information](#) and [Medication Guide](#), including **serious side effects**.

Important Safety Information for MAVENCLAD® (cladribine) (continued)

- **serious infections such as:** (continued)
 - **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® (cladribine), 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.** 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. Your doctor will perform blood tests to check your liver during treatment.
- **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 heartbeat, 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.

To report SUSPECTED ADVERSE REACTIONS, contact EMD Serono at: 1-800-283-8088 ext. 5563 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full [Prescribing Information](#) and [Medication Guide](#), including **serious side effects**.

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