

Your healthcare provider will continue to monitor your health during the 2 yearly treatment courses, as well as between treatment courses and for at least another 2 years, during which you do not need to take MAVENCLAD. Your healthcare provider may delay or completely stop treatment with MAVENCLAD if you have severe side effects. It is not known if it is safe and effective for people to restart MAVENCLAD after the full 4-year period.

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.

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 fetal harm, 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 9-10.

MAVENCLAD®
(cladribine) tablets 10 mg

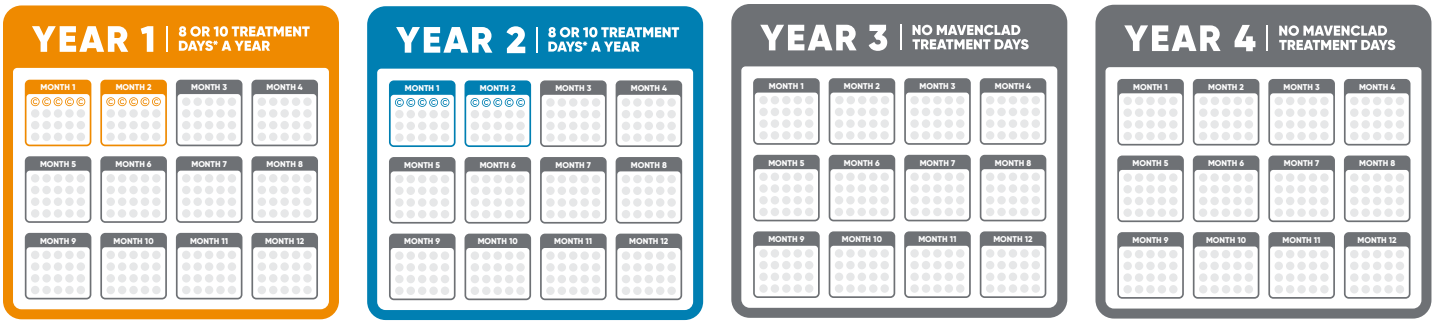
Convenient dosing

MAVENCLAD is the first short-course oral therapy with **no more than 10 treatment days a year for 2 years.**

MAVENCLAD is taken over 2 weeks in the first year and over 2 weeks in the second year.

For each week of treatment, you'll take 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. Then, you don't have to take MAVENCLAD for the rest of the year.

The number of pills you take per day will depend on your weight. Your health will be monitored before, during, and after treatment.



*1 or 2 pills a day depending on your weight

What happens once you've taken MAVENCLAD

Your healthcare provider will continue to monitor your health during the 2 yearly treatment courses, as well as between treatment courses and for at least another 2 years, during which you do not need to take MAVENCLAD. Your healthcare provider may delay or completely stop treatment with MAVENCLAD if you have severe side effects.

Important Safety Information (cont'd)

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.

- Ask your healthcare provider which contraceptive method is right for you. Females and males 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 for females, and 14 weeks for males.

Please see **Important Safety Information** on pages 9-10.

How MAVENCLAD was studied

MAVENCLAD was studied in a 96-week clinical trial with relapsing MS patients to measure how well it works and to evaluate its safety.

433 PEOPLE TOOK MAVENCLAD

92% completed the full **96** weeks of the study

437 PEOPLE TOOK A PLACEBO

87% completed the full **96** weeks of the study

Proven results of MAVENCLAD

Here's how MAVENCLAD performed when compared to placebo in a 96-week clinical study.

Reduces the rate of relapses

58% REDUCTION

IN RELAPSE RATE
compared to **PLACEBO**

MAVENCLAD 0.14 vs placebo 0.33

81% OF MAVENCLAD PATIENTS

were relapse-free
compared to

63% ON PLACEBO
at the end of the clinical trial

Important Safety Information (cont'd)

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. MAVENCLAD can pass into your breast milk and may harm your baby. Do not breastfeed on the days you take MAVENCLAD, and for 10 days after the last dose.

Please see **Important Safety Information** on pages 9-10.



Significantly decreases development of new and active lesions

Patients taking MAVENCLAD had fewer lesions compared to patients not taking MAVENCLAD.

The number of lesions can be seen through the 2 types of magnetic resonance imaging (MRI) scans typically used with MS.

86% FEWER

ACTIVE, INFLAMED LESIONS

Average number of T1-Gd+ lesions: MAVENCLAD 0.12 vs placebo 0.91.

At 96 weeks, **13.2% (57 out of 433)** of patients in the MAVENCLAD group had T1-Gd+ lesions vs **51.7% (226 out of 437)** of patients in the placebo group.

73% FEWER

NEW & ENLARGING LESIONS

Average number of active T2 lesions: MAVENCLAD 0.38 vs placebo 1.43.

At 96 weeks, **38.3% (166 out of 433)** of patients in the MAVENCLAD group had active T2 lesions vs **71.6% (313 out of 437)** of patients in the placebo group.

T1-Gd+ = gadolinium-enhancing (Gd+) lesions.

Important Safety Information (cont'd)

How should I take MAVENCLAD?

- MAVENCLAD is given as two yearly treatment courses, consisting of 2 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.

Please see **Important Safety Information** on pages 9-10.

Reduces disability progression*

MAVENCLAD kept **87% of patients** free from 3-month confirmed Expanded Disability Status Scale (EDSS) progression vs **81% on placebo**.

33%
LESS LIKELY
to have disability progression
compared to **PLACEBO**

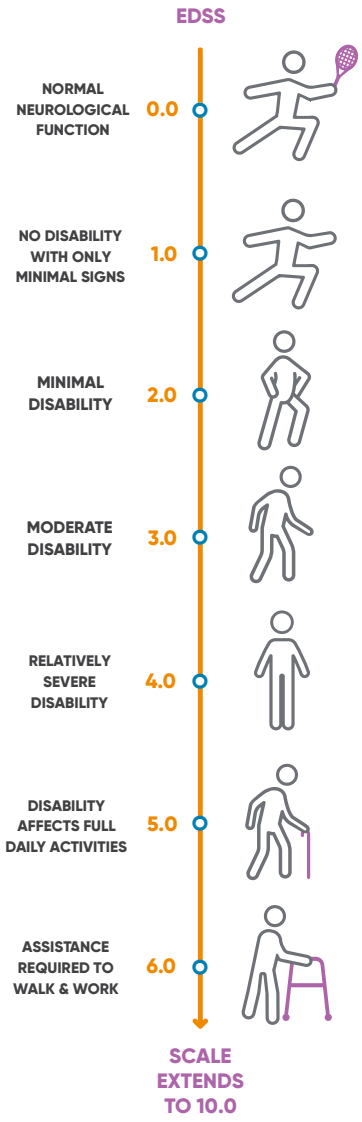
APPROXIMATELY
9 OUT OF 10
MAVENCLAD PATIENTS had
no disability progression compared to
8 OUT OF 10 FOR PLACEBO

*Disability progression was defined as an increase of at least 1 point in the EDSS that was sustained for at least 3 months.

EDSS = Expanded Disability Status Scale.

How is disability progression measured?

Disability progression is a common measure of MS treatments in clinical trials. It can be charted on the EDSS.



Important Safety Information (cont'd)

How should I take MAVENCLAD (cont'd)?

- 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.

Please see **Important Safety Information** on pages 9-10.

The safety profile of MAVENCLAD has been extensively evaluated

When it comes to choosing a relapsing multiple sclerosis (MS) treatment, safety is a key factor. Clinical trial evaluations, follow-ups, and real-world experience support the safety profile of MAVENCLAD.

MAVENCLAD SAFETY PROFILE HAS BEEN EVALUATED FOR 20+ YEARS



Common side effects seen in clinical trials

Some of the most common side effects experienced by patients included:



UPPER RESPIRATORY INFECTION

PATIENTS ON MAVENCLAD	38%
PATIENTS ON PLACEBO	32%



HEADACHE

PATIENTS ON MAVENCLAD	25%
PATIENTS ON PLACEBO	19%



LYMPHOPENIA (low white blood cell count)

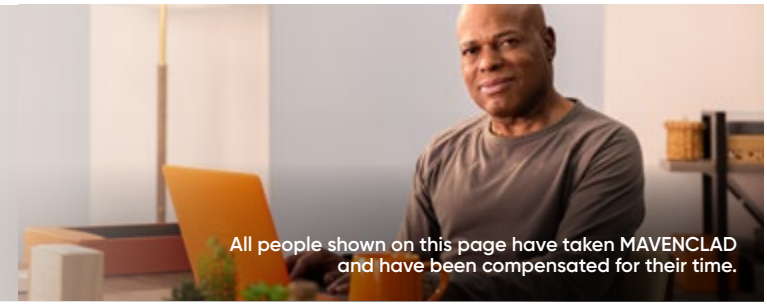
PATIENTS ON MAVENCLAD	24%
PATIENTS ON PLACEBO	2%

The types and seriousness of side effects vary from patient to patient. For a list of possible, serious side effects, including the risk of cancer (malignancies) and birth defects, please see the Medication Guide. This is not intended to replace discussions with your healthcare provider. If you think you are experiencing any of these side effects or symptoms, please talk to your healthcare provider immediately.

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 **Important Safety Information** on pages 9-10.

Brand-name MAVENCLAD and generic substitution



All people shown on this page have taken MAVENCLAD and have been compensated for their time.

Understanding your prescription

Brand-name MAVENCLAD is an oral, high-efficacy treatment option for RMS. More than 130,000 people with RMS globally have been prescribed brand-name MAVENCLAD, with a safety profile evaluated for 20+ years.*

When a prescription is filled, it's helpful to understand that pharmacies may dispense a generic version of cladribine instead of brand-name MAVENCLAD, depending on state regulations and how the prescription is written. Generic medications are approved by the FDA and are required to meet standards for quality, safety, and effectiveness.

For some patients, healthcare providers may choose to specify brand-name MAVENCLAD on the prescription. If you have questions about your treatment or how your prescription will be filled, your healthcare provider or pharmacist can help explain what to expect.

Talking with your healthcare provider

If you and your healthcare provider decide that brand-name MAVENCLAD is right for you, it may be helpful to discuss how your prescription will be written, whether brand-name or generic cladribine may be dispensed, and what questions to ask your pharmacist when filling your prescription.

State rules around generic substitution can vary, and prescription requirements may differ depending on where you live. Your healthcare provider is the best resource for understanding how these rules apply to your treatment plan.

Support available with brand-name MAVENCLAD

Patients prescribed brand-name MAVENCLAD may have access to 1:1 patient support and other helpful resources designed to assist throughout treatment. These resources can help with understanding insurance coverage, medication delivery, and what to expect during and after therapy.

If you have questions about your prescription or available resources, your healthcare provider can help guide you to additional information.

RMS = relapsing multiple sclerosis.

*Including clinical trial evaluations, follow-ups, and real-world experience.

Important Safety Information (cont'd)

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

Please see **Important Safety Information** on pages 9-10.

MS support you can count on

MS LifeLines is a patient resource sponsored by EMD Serono that provides financial and treatment support for eligible patients through Patient Support Specialists and MS-certified nurses.

Financial assistance for eligible patients

EMD Serono is committed to ensuring all eligible patients who have been prescribed MAVENCLAD have access to treatment.

If you're eligible* and have commercial insurance, you may pay as little as $0 co-pay or co-insurance for MAVENCLAD.

$0 CO-PAY
OR CO-INSURANCE
FOR MAVENCLAD

MS LifeLines also offers other assistance programs, including free medication, to help eligible patients gain access to MAVENCLAD.

*Some limitations are required by law. Patients covered by federal or state healthcare programs, including Medicare and Medicaid, are not eligible for assistance. This program is open to residents of the U.S. and Puerto Rico with relapsing forms of multiple sclerosis who are starting MAVENCLAD therapy or presently taking MAVENCLAD.

Patient Support Specialists can:

- **Help verify insurance benefits** to determine coverage and help you understand how much money you may have to pay for your medication (out-of-pocket expenses)
- **Provide information** about MS LifeLines financial assistance options and help determine if you qualify
- **Work with specialty pharmacies** to facilitate treatment access and help coordinate treatment delivery

MS LifeLines Nurses are there for you

MS-certified nurses support you before, during, and in between treatment by providing educational resources and information to help you understand and stay on track with MAVENCLAD.

MS LifeLines Nurses can:

- **Help you with your treatment** during your 2 years on MAVENCLAD
- **Provide tips and MS education** to help manage certain symptoms

Connect with MS LifeLines

Call us at **1-877-447-3243**

Monday through Friday • 8 AM to 8 PM ET

Please see **Important Safety Information** on pages 9-10.

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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.
  - Ask your healthcare provider which contraceptive method is right for you. Females and males 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 for females, and 14 weeks for males.

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. MAVENCLAD can pass into your breast milk and may harm your baby. Do not breastfeed on the days you take MAVENCLAD, and for 10 days after the last dose.

(continued)

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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.
  - **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.** 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**.

MAVENCLAD®
(cladribine) tablets 10 mg

IT'S TIME

TO ASK ABOUT MAVENCLAD.

Talk to your healthcare provider and ask if MAVENCLAD is right for you.

Please see full Prescribing Information and Medication Guide, including **serious side effects**.

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